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Maryland Pharmacist

VOLUME 82 NO. 1

2006 Maryland Leadership Elections
Statements of the Candidates and Official Ballot

Recognizing Pharmacy Excellence
MPha 2006 Awards Nomination Form

Continuing Education
"Recommendations for Prevention and Control of Influenze: 2005-06 Flu Season"

MARYLAND PHARMACISTS ASSOCIATION JAN./FEB./MARCH 2006

Maryland Pharmacists Association

650 W. Lombard Street
Baltimore, MD 21201
410-727-0746
www.marylandpharmacist.org

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Maryland Pharmacist

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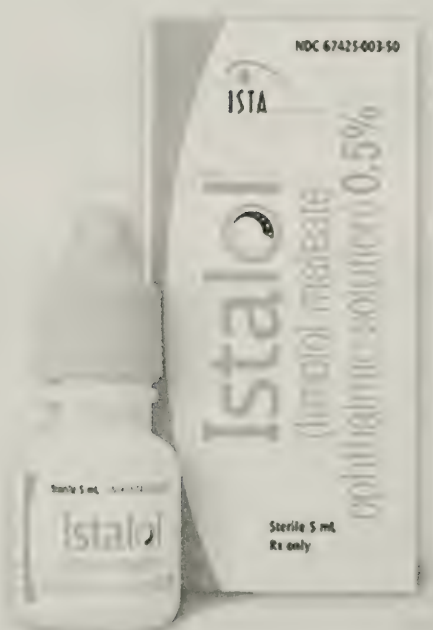

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URGENT

Important information for pharmacists treating patients with glaucoma

FDA: Generic Substitution for BT-Rated Meds Carries Risk

The Legal Necessity of Ensuring Bioequivalence

The FDA grants BT ratings only to drugs with no recognized bioequivalent.

Bioequivalent drugs, according to the Orange Book, "can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling." The Orange Book remains the definitive authority on drug bioequivalence.

Pharmacists may be unaware that ophthalmic beta-blocker Istalol® (timolol maleate ophthalmic solution) 0.5% carries a BT rating.* No drug is bioequivalent to Istalol®. *It may be illegal in your state to substitute BT-rated products.* Check pharmacy laws in your state. Such substitutions have the potential to place a pharmacist's professional license and personal assets at risk. Moreover, a pharmacist who substitutes a drug that is not bioequivalent may be negligent and, should that negligence result in injury to a patient, a legal cause of action may be established against that pharmacist.

"Istalol® carries a BT rating. No drug is bioequivalent to Istalol®."

How can pharmacists ensure they are selecting bioequivalent medications, thereby protecting themselves and their patients? *Pharmacists should refer to the FDA authoritative source, the Orange Book.* In many states, the Orange Book is the only official reference for bioequivalence. Caution must be used when employing pharmacy software programs that only list generic equivalents and do not indicate whether a drug has a BT rating.

As clearly indicated by the FDA BT rating, no other product, including generic timolol, is therapeutically equivalent to Istalol®, and therefore cannot be substituted for it. To do so may be a violation in your state.

*FDA Orange Book 2005.
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Greetings!

Well we are into the first Quarter of 2006! I hope that everyone rested before the New Year because it has been a rather "busy" time since. We have seen the implementation of Medicare Part D and the issues that it brought. The program had its many and might I say well documented problems, but with any new program as sweeping as Medicare Part D we knew that it would not be a smooth transition. Despite all the agony we and our patients endured through this process we as a profession became stronger. Pharmacy in most instances was seen as the steady face for our patients, trying to work through the system (many times for hours on end), making sure that our patients continued with their medications in spite of uncertainty for re-imbursement or confusion about the patients coverage (or lack there of). I personally want to THANK YOU for showing the country that we do care and I believe we have found new respect from many quarters. As I said before we are the "go to" experts that Pharmacists have been for many years and will continue to be for the years ahead.

Our Mid-Year meeting in January was a success as well as filled with timely topics. Thanks to Howard, Elsie, Nancy, and especially Convention Committee Chair and soon to be President Ginger Apyar. Without your help these meetings would never get off the ground and be as successful as they are.

February the 16th brought our sixth annual Legislative day in Annapolis. The Maryland Pharmacy Collation with its member organizations spearheaded this important task; we at MPhA want especially thank Murhl Flowers for his guidance and time. We face many issues in the current session both locally and nationally. The Technician bill, Pseudo-ephedrine monitoring, tracking of CDS prescriptions, difficult issues with a potential conscious clause, and many others. Legislative Day is just the beginning; we must be active on these many legislative issues on a continual basis. Call or better yet meet with your local political representatives and let them know how these issues affect you and your profession. I would be remise not to mention the bills that affect us professionally but just as importantly economically! Please keep in touch with the ever changing political landscape and give our organization feed-back and questions should they arise. Howard is very busy with these efforts and needs our help; you can call or utilize our website at www.marylandpharmcist.org.

Our committees are busy working on many tasks. The Communication Committee headed by Doris Voight is trying to put a new face on our newsletter as well as help our web-master upgrade and improve our website. The membership committee is sending applications to the over 5,000 Pharmacists residing or practicing Pharmacy in Maryland as we speak. It is imperative that we increase our membership to keep this a viable organization. The Professional programs committee has been working diligently. We are currently busy with Immunization training, Medication Management Therapy (MTM) partnering with Outcomes, and many other projects that will be "grabbing" your attention shortly. I have already mentioned the Convention Committee and believe it or not the Annual Convention June 10th-13th in Ocean City is just around the corner. We are soliciting resolutions for the House of Delegates to consider, Speaker of the House Mary Kremzner would be happy to hear from you even if the resolution is just and idea, she will work with you to put the idea into the form of a resolution (you can e-mail the Association to her attention).

As you can see there is a lot going on and we want all of our members to feel welcome and share their views and ideas with the Association.

Thank You Again!
Matthew Shimoda, Pharm.D.
President

"Therapeutically Speaking..."

"New Therapeutic Options for Patients with Diabetes"

Kellie Monzillo, Pharm.D. Candidate 2006

Adult patients with diabetes gained new adjunctive treatment options with the introduction of two new classes of antihyperglycemic drugs in the spring of 2005. In April, Amylin Pharmaceuticals along with Eli Lilly and Company received FDA approval of exenatide (Byetta) for type 2 diabetes just one month after Amylin had received approval of pramlintide (Symlin) for type 1 and type 2 diabetes. Both products are only available as subcutaneous injections and have been shown to improve glycemic control without the unwanted side effect of weight gain that has been a limitation of several other available hypoglycemic agents.

Exenatide (Byetta)

Exenatide is the first in a new class of antidiabetic medications referred to as incretin mimetics. Exenatide is indicated as adjunctive therapy to improve glycemic control in adult patients with type 2 diabetes who are taking oral antidiabetic medications (metformin, sulfonylurea, or a combination of metformin and a sulfonylurea) who have not attained adequate glycemic control on these oral medications alone.[1]

Incretin hormones contribute to glycemic control by several mechanisms including enhanced glucose-dependent insulin synthesis and release, decreased glucagon secretion, and slowed gastric emptying.[2] Glucagon-like peptide-1 (GLP-1) is responsible for 70-80% of the incretin effects in normal individuals and its release is impaired in patients with type 2 diabetes.[3] Exenatide is a GLP-1 receptor agonist and mimics its antidiabetic effects. Following exenatide administration, insulin secretion is enhanced in response to increases in glucose concentration and inappropriate glucagon secretion is inhibited, decreasing hepatic glucose production.[2] Additionally, exenatide slows gastric emptying resulting in slowed glucose absorption and overall decreased food intake.[2] The combined effects result in reductions in postprandial and fasting glucose concentrations, glycated hemoglobin (referred to as A1c), and body weight.

In three randomized controlled trials, patients taking metformin, sulfonylurea, or combined metformin and sulfonylurea therapy were randomized to receive exenatide 5 mcg, 10 mcg or placebo twice daily for 30 weeks in addition to their existing antidiabetic agent. In all three trials, patients taking exenatide showed dose dependent decreases in A1c (approximately 0.8%), fasting and postprandial glucose, and decreased body weight as compared to placebo groups.[4,5,6]

The recommended starting dose is 5 mcg injected subcutaneously twice daily at any time within the 60 minute period before the morning and evening meals. Exenatide should not be administered after a meal.[1] If necessary, following one month of therapy the dose may be increased to a maintenance dose of 10 mcg twice daily before meals.[1] Exenatide is supplied as a 250 mcg/ml solution in either 1.2 ml or 2.4 ml prefilled pens. Subcutaneous injection with the pen may be administered in the abdomen, thigh, or upper arm.

Exenatide is not indicated for use in patients with type 1 diabetes and is not a substitute for insulin in insulin-requiring patients with type 2 diabetes. Exenatide is extensively eliminated by the kidney and therefore patients with severe renal impairment (CrCl< 30ml/min) should not use exenatide. Safety in children has not been established and exenatide is not indicated for pediatric use.[1]

The most common adverse effects of exenatide are nausea and vomiting. Nausea is experienced by up to 44% of patients initiated on exenatide, although this dose-related effect may be minimized by gradual dosage titration.[7] The occurrence of nausea is more pronounced early on in therapy and usually subsides with continued use.[3] Other adverse effects can include diarrhea, dizziness, headache, and nervousness.

When given adjunctively with metformin, the incidence of hypoglycemia is no different from placebo. However, when exenatide is administered with medications that may induce hypoglycemia (such as a sulfonylurea agent) the incidence of hypoglycemia increases. Hypoglycemia is dose dependent based on doses of both exenatide and the sulfonylurea.[7] Dose reduction of the sulfonylurea should be considered when adding exenatide to reduce the risk of hypoglycemia.[2]

Because exenatide slows gastric emptying, it may reduce the rate and extent of co-administered oral medications. For example, exenatide has been shown to decrease the bioavailability of lovastatin and acetaminophen.[7] Medications such as antibiotics and oral contraceptives that require threshold concentrations for efficacy should be administered at least one hour before administering exenatide.[2] The effect of exenatide on the clinical effectiveness of oral contraceptive therapy has not been studied.

Exenatide should be considered as adjunctive therapy in patients with type 2 diabetes who are currently maximized on metformin, a sulfonylurea, or a combination of metformin plus sulfonylurea who are not reaching their glycemic goals and for whom weight control is a consideration. Some patients may be fearful or reluctant to begin a medication that requires subcutaneous injection, and will require education from the pharmacist. Monitoring for patients on exenatide should include routine monitoring of blood glucose, A1c, and weight as well as signs and symptoms of hypoglycemia.[7]

Pramlintide (Symlin)

Pramlintide, the first in a new class of antihyperglycemic medications known as amylinomimetics, is indicated for use with insulin in adults with type 1 or type 2 diabetes who are unable to achieve adequate glycemic control despite intensive insulin therapy.[8]

Amylin is an endogenous neuroendocrine hormone that is co-secreted with insulin from pancreatic beta cells in response to increases in blood glucose. Amylin exerts its effects on blood glucose by slowing gastric emptying, regulating food intake by reducing appetite, and by decreasing hepatic glucose production through inhibition of postprandial glucagon secretion.[8] The release of amylin and insulin is significantly reduced in patients with type 1 and insulin-requiring type 2 diabetes following food intake.[2]

Pramlintide, a synthetic analog of human amylin, mimics the effects of endogenous amylin. Results of pramlintide clinical trials demonstrate efficacy in decreasing postprandial glucose concentration, reducing glucose fluctuation and decreasing food intake.[8] Studies in patients with type 1 and type 2 diabetes show a decrease in A1c by approximately 0.4% and patients were able to slightly reduce their total daily dose of insulin.

During clinical trials, the most commonly reported adverse effects were nausea, headache, anorexia, vomiting, abdominal pain, and inflicted injury.[8] Nausea, the most common side effect, is seen when therapy is initiated and is minimized with slow dosage titration and lessens over time with continued therapy.[3] Pramlintide alone does not cause hypoglycemia, but when added adjunctively to insulin therapy, it increases the risk of insulin-induced hypoglycemia.[8]

Patients should be considered for pramlintide therapy if they have been unable to achieve glycemic goals with individualized insulin regimens alone and only if their diabetes is closely managed by a healthcare professional. Contraindications for pramlintide use are hypoglycemic unawareness or a confirmed diagnosis of gastroparesis. Also, pramlintide therapy should not be considered if patients have an A1c > 9%, show poor adherence to insulin therapy or self-blood glucose monitoring, have recurrent episodes of severe hypoglycemia, or require drugs that alter gastrointestinal motility.[8] Pramlintide's safety and efficacy has not been established in pediatric patients and therefore is not indicated for use in this population.

Dosing of pramlintide differs between patients with type 1 and type 2 diabetes. For type 1 diabetes, the recommended starting dose of pramlintide is 15 mcg subcutaneously (SC) before major meals (defined as $\geq$ 250 kcal or $\geq$ 30 grams carbohydrate). The dose of preprandial, rapid-acting, or short-acting insulin dosages, including fixed-mix insulins (e.g., 70/30) should be reduced by 50% when initiating pramlintide. The dose of pramlintide may be increased in 15 mcg increments when no clinically significant nausea has been present for at least three days.[8] In patients with type 2 diabetes, the recommended starting dose is 60 mcg SC before major meals and should be titrated to 120 mcg before major meals as tolerated.[8] The same precautions apply to patients with type 2 diabetes regarding insulin dosage reduction when initiating pramlinitide, and only increasing pramlintide dose with nausea resolution. For all patients the insulin regimen should be adjusted once the final pramlintide dose is established.

Pramlintide is supplied in 5 ml vials containing 0.6 mg/ml pramlintide acetate. To administer pramlintide from vials, the patient should be instructed to use a U-100 insulin syringe (0.3 ml size) using the conversion table shown (Table 1).
(Continued on page 20)

Statements of the Candidates

Treasurer

Walter Abel, R.Ph.
I, Walter Abel, with respect and appreciation, accept the Board's nomination for a second term as Treasurer of the Maryland Pharmacists Association.

Pharmacy has always been my profession and it is in the interest of promoting the profession that I want to continue to be part of the Board meetings and participate as an interested member. I am thankful for being given the opportunity to serve as Treasurer during the past year and promise to continue to conscientiously and prudently watch over the organization's finances. Thank you for the nomination and your continued support.
Walter H. Abel

Trustee Seat # 1

Doug Campbell, R.Ph.
I have been a member of the MPhA Board of Trustees for the past few years, and serve as volunteer Curator of the B. Olive Cole Pharmacy Museum at Kelly Memorial Building—MPhA's headquarters. I would be honored to continue to serve on the Board to further improve and develop the Profession of Pharmacy here in Maryland, and to continue to serve in the development of The Maryland Pharmacists Association.

Mary E. Kremzner, Pharm.D.,
CDR United States Public Health Service (PHS)
Deputy Director, Division of Drug Information
Office of Training and Communication
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

My practicing pharmacy experience has been with chain pharmacy, independent community pharmacy and my current position in federal government. Throughout my 19-year career, I have continuously worked in a community pharmacy position and currently maintain my skills as a practicing pharmacist by working part-time for Watermont pharmacy.

At this time, I serve full-time as the deputy director in the FDA's Division of Drug Information. In this capacity, I supervise a staff of 20 that consists mainly of Pharm.D.s. The Division is charged with the responsibility of responding to inquiries from a broad range of sources, including regulated industry, academia, health care professionals, consumers, and others. I joined the agency in 1996 and have served in various capacities as a pharmacist. *(Continued on page12)*

(Continued from page 11)
Having served as the Vice Speaker in 2005 and now Speaker of the House in 2006, I see how important a role MPhA plays for all Maryland pharmacists. The MPhA must remain an active and vital part of the Maryland pharmacist community and this can be done by reaching out to all who practice the profession. Promotion of the MPhA, what it does and what it can do for all pharmacists in Maryland, is of paramount importance to the future well being of the our profession. As I have been privileged to work various fields of pharmacy, I would consider serving as a Trustee in the MPhA an even greater privilege.

I am a graduate of the University of Maryland, School of Pharmacy with a Bachelor of Science Degree in Pharmacy in 1987 and a Pharm.D. in 1998.

Trustee Seat #2

Butch Henderson, P.D.

After graduating from University of Maryland School of Pharmacy in 1988, I began working as a pharmacist for Klein's Family Markets in Harford County. In 1992, I became the pharmacy director and now oversee 7 stores in Harford and Baltimore Counties. I have been privileged to serve MPhA as a trustee since 2000 and am honored to be nominated again. I believe that we are in the midst of an amazing opportunity to show the public what we do and just how knowledgeable and valuable we are as pharmacists. Many people think of recent events as obstacles: Y2K, HIPAA, Medicare Drug Plans; but we must be forward thinking and look for the opportunities in these events. Pharmacists must step up and show the public what we can do, and in most cases these are things you are already doing, now—show them, tell them, and bill them! Yes, with MTM you can be paid for things that you already are doing! Contrary to what some public and government heads think, pharmacy is more than the cost of a drug. The value of pharmacy is in services, drugs, education, therapy management. Now is the time to show this and share this. We must defend our profession and show the value of our services. Organizations like MPhA are working to promote pharmacy, the profession, not just a segment: "retail", "independent", "institutional", … but pharmacy as a whole. With the coordinated efforts of organizations and pharmacists we can continue to be strong, and maybe we will encourage our kids to be pharmacists after all. Thank you for your consideration.

John VanWie, P.D.

It is an honor and delight to be nominated for Trustee of the MPhA. As a 1984 graduate of University of Maryland my entire career has been in retail pharmacy. Trained with Peoples Drug Store, pre-CVS, since 1985 I have been with Safeway in various management positions with my concentration of recent years in business development. As an MPhA member since graduation and more recently holding positions of Vice Speaker (2003) and Speaker of the House (2004-2005), it is my strong belief we need to make a contribution to the profession by sharing what we have learned throughout our careers. MPhA is one group that enables us make this contribution and it would a privilege to be your Trustee. Thank you for your consideration.

2006 Maryland Leadership Elections
Official Ballot

Please select the candidate you believe will best fulfill the duties of the office by checking the box appearing beside their name.

Maryland Pharmacists Association Officers

Treasurer

☐ Walter Abel, R.Ph.

Please select the candidate you believe will best represent you as a member on the Board of Trustees by checking the box appearing beside their name.

Maryland Pharmacists Association Board of Trustees

Trustee Seat # 1

☐ Doug Campbell, R.Ph.

☐ Mary E. Kremzner, Pharm.D.

Trustee Seat # 2

☐ Butch Henderson, P.D.

☐ John VanWie, P.D.

When completed, seal and return your self-mail ballot to the Maryland Pharmacists Association, ***received by Friday, May 5, 2006***. For questions, please call MPhA at 800-833-7587.

Fold

2006 Maryland Leadership Elections
Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

Fold

Maryland Pharmacists Association
Constitution and Bylaws

Constitution

Article I. Name

This Association shall be known as the Maryland Pharmacists Association and shall be abbreviated "MPhA".

Article II. Mission

The mission of MPhA is to promote excellence in pharmacy practice, strengthen the profession of pharmacy, and advocate for all Maryland Pharmacists.

Article III. Purpose

The purpose of MPhA is to promote:

- The health and well-being of Maryland citizens.
- Safe and effective use of medications and health care devices.
- Collaboration among health care professionals and organizations.
- Professional competence.
- Leadership development.
- Responsible legislation and regulation.
- The history and tradition of Maryland Pharmacy.

Article IV. Membership

A. Active Membership

Any pharmacist in good professional standing who has a valid license to practice pharmacy in any state is eligible to become an active member.

B. Other Categories of Membership

The Board of Trustees shall establish other categories of membership as it deems appropriate.

Article V. Governing Body

The Governing Body of the MPhA shall be the Board of Trustees.

The Board of Trustees shall provide supervision, control, and direction of the affairs of the Association; shall implement policies established by the House of Delegates, making changes if necessary within the limits of the Bylaws; shall actively pursue the purposes of the Association; and shall have the final discretion in the disbursement of its funds. It may adopt procedures for the conduct of its business, and may, in the execution of the powers granted, appoint such agents as it may consider necessary.

The Board of Trustees must approve all contracts entered into on behalf of the Association by the President or Executive Director.

The Board of Trustees shall ratify the slate of At-Large and Independent nominees for appointment to the Board of Pharmacy.

Article VI. Officers

The Officers of the MPhA shall be active members of the Association and consist of the President, Vice President (who shall be the President-elect), Treasurer, and the Immediate Past President (who shall serve as Chairman of the Board of Trustees).

Article VII. Executive Committee

The Chairman of the Board of Trustees, the President, Vice President, Treasurer, Speaker of the House of Delegates, and the Executive Director (in an ex-officio capacity) shall constitute the Executive Committee. The Executive Committee may exercise the powers of the Board of Trustees for emergency business when the Board of Trustees is not in session, reporting to the Board of Trustees any action taken. Three (3) members shall constitute a quorum for the transaction of business. A meeting may be called by the Chairman of the Board of Trustees or the President.

Simultaneous with the preparation of the proposed yearly budget by the Budget and Finance Committee, the Executive Committee shall conduct a performance review of the Executive Director and if appropriate negotiate changes in the Executive Director's compensation and benefits. Any changes in compensation and benefits shall be shared with the Budget and Finance Committee and presented to the Board of Trustees for approval.

Article VIII. Legislative Body

The Legislative Body of the MPhA shall be the House of Delegates.

The House of Delegates shall be charged with the following duties and responsibilities: serve as the policy making body of the Association; consider and implement by resolution, action, or other manner all appropriate proposals emanating from the membership; receive reports of Association Officers and Committees; adopt rules for the conduct of business; ratify the slate of Officers and trustees for election; and approve all proposed constitution and Bylaws changes prior to a vote of the Association members.

Article IX. Parliamentary Authority

The Rules of Order of the Board of Trustees shall be the version of "Robert's Rules of Order" approved by the Board of Trustees.

The Rules of Order of the House of Delegates shall be the version of "Robert's Rules of Order" approved by the House of Delegates.

Article X. Amendment of Constitution

Every proposal to amend this Constitution must be submitted in writing to the Constitution and Bylaws Committee. After prudent consideration the committee shall present its recommended changes to the Board of Trustees. The proposed changes shall be presented to the membership at a regular or special meeting of the House of Delegates. Upon the affirmative vote of at least two-thirds of the delegates present at this meeting, a vote of the Association members shall be conducted.

A proposed amendment shall then become part of the Constitution with an affirmative vote of at least two-thirds of the responders.

Bylaws

Article I. Membership

A. Dues

The annual dues for each category of membership of the Association shall be determined by the Board of Trustees. Members who fail to pay their dues within a period specified for each category of membership by the Board of Trustees shall be notified by the Executive Director. If payment is not made within a grace period specified by the Board of Trustees, without further notice and without hearing, the delinquent members shall be dropped from the Association rolls and thereupon forfeit all rights and privileges of membership including but not limited to the right to hold office, the right to vote in elections, the right to serve as a Delegate, privileges of member discounts, and eligibility for member only promotions. The Board of Trustees may establish procedures for extending the time for payment of dues and continuation of membership privileges upon request of a member showing good cause.

B. Meetings

The Association shall meet at least two times during the year at times set by the Board of Trustees. One meeting shall be know as the Annual Meeting and one shall be known as the Mid Year Meeting.

Article II. Board of Trustees

A. Composition

The Board of Trustees shall be composed of thirteen (13) members which shall include the following Officers: Immediate Past President, who shall serve as Chairman; President; Vice President, who shall be the President-elect; Treasurer; Speaker of the House of Delegates; Vice Speaker of the House of Delegates, who shall be the Speaker-elect; six(6) elected Trustees; and one(1) Trustee who is the President or designee of the Academy of Student Pharmacists of the University of Maryland School of Pharmacy.

Ex-officio members of the Board of Trustees shall include the Executive Director of the Maryland Pharmacists Association, the Dean of the University of Maryland School of Pharmacy, and the President or designee from each of the following organizations: the Maryland Society of Health System Pharmacists, the Maryland Chapter of the American Society of Consultant Pharmacists, and the Maryland Pharmaceutical Society. No ex-officio member shall have voting privileges.

B. Terms of Office

Elected Trustees shall serve for staggered three (3) year terms, two (2) elected each year. Any Trustee shall be eligible for reelection up to a maximum of three (3) consecutive terms. A vote by the Association members to elect the Trustees shall be initiated within sixty (60) days after nominations have been certified by the House of Delegates. The results of the election shall be reported to the Board of Trustees by a Canvassing Committee appointed by the President. Newly elected Trustees, upon installation, immediately enter upon the performance of their duties and shall continue in office until their successors are elected and installed, or unless they resign, are removed, or are otherwise unable to fulfill an unexpired term.

C. Meetings of the Board of Trustees

The Board of Trustees shall have regular meetings throughout the year, including a meeting at the time and place of the Annual Meeting. The Board shall meet upon call of the Chairman of the Board, or President at such times

and places that may be designated, and shall be called to meet upon demand of a majority of the Board. Notice of all meetings of the Board of Trustees shall be transmitted to the last recorded address of the Board member at least ten (10) days in advance of such meetings. With the exception of executive sessions, where confidential issues are discussed, all regular meetings of the Board of Trustees are open to the general membership.

D. Quorum

A majority of the whole Board shall constitute a quorum at any meeting of the Board.

E. Absences

If a member of the Board of Trustees is absent from three (3) consecutive meetings for reasons which the Board has declared to be insufficient by a two-thirds majority vote of the entire Board of Trustees, and if the Trustee is given reasonable prior notice of the potential removal, resignation shall be deemed to have been tendered and accepted.

F. Compensation

Trustees shall not receive compensation for their services as Trustees, but the Board may, by resolution, authorize reimbursement of expenses incurred in the performance of their duties. Nothing herein shall preclude a Trustee from serving the Association in any other capacity and receiving compensation for such services.

G. Resignation or removal

Any Trustee may resign at any time by giving written notice to the President, the Executive Director or to the Board of Trustees. Such resignation shall take effect at the time specified therein, or if no time is specified, at the time of acceptance thereof as determined by the Chairman of the Board. Any Trustee may be removed by a two-thirds majority vote of the entire Board of Trustees.The Trustee shall be given reasonable prior notice of the potential removal and the reasons for removal.

H. Vacancies

Any Trustee vacancy that may occur on the Board by reason of death, resignation, or removal shall be filled by a majority vote of all remaining members of the Board for the unexpired term.

I. Indemnification

As used in this Article, any word or words defined in section §2 -418 of the Corporations and Associations Article of the Annotated Code of Maryland, as amended from time to time, (the "Indemnification Section") shall have the same meaning as provided in the Indemnification Section.

This Association shall indemnify and advance expenses to a Trustee or Officer of the Association in connection with a proceeding to the fullest extent permitted by and in accordance with this Indemnification Section. With respect to an employee or agent, other than a Trustee or Officer of the Association, the Association may, as determined by the Board of Trustees of the Association, indemnify and advance expenses to such employees or agent in connection with proceedings to the extent permitted by and in accordance with the Indemnification Section.

Article III. Officers

A. Terms of Office and Elections

The President shall be a non-elected position. The Vice President (who will be the President-elect) shall be elected annually and the Treasurer shall be elected biannually by a vote of the Association members initiated within sixty (60) days after nominations have been approved by the House of Delegates. The results shall be reported to the Board of Trustees by a Canvassing Committee appointed by the President.

B. Installation

Each officer shall take office upon installation and shall assume the duties of his or her office and shall serve for the stated term of office or until the successor is duly elected and installed.

C. Vacancies

Except for vacancies in the position of President, which shall be filled by the Vice President, and Speaker of the House of Delegates, which shall be filled by the Vice Speaker, vacancies in all other offices shall be filled for the balance of the term thereof by an individual elected by a majority vote of the entire Board of Trustees.

D. President

The President shall be the principal officer of the organization and shall preside at membership meetings of the Association. In the absence of the Chairman of the Board of Trustees, the President shall preside at meetings of the Board of Trustees and of the Executive Committee. The President shall be an ex-officio member of all committees with right to vote. The President shall submit a report at the Annual Meeting of the Association.

E. Vice President (who shall be the President-elect)

The Vice President shall be the President-elect, and in the event of the temporary disability or absence of the President and with the approval of the Board of Trustees, shall assume and perform the duties of President until the President is able to resume such duties.

The Vice President shall have such duties as the President and the Board of Trustees may assign. The Vice President shall be an ex-officio member of all committees with right to vote. The Vice President shall chair the Nominating Committee and present a report of the Committee at the Mid-Year Meeting. Upon completion of his/her term of office, the Vice President shall automatically assume the office of the President.

F. Treasurer

The Treasurer shall ensure the maintenance of an account of all monies received, invested, and expended by the Association; shall oversee disbursements authorized by the Board of Trustees; and shall make a report at the Annual Meeting or when called upon by the President. All sums received shall be deposited in institutions approved by the Board of Trustees. Funds may be drawn only upon the signature of the Treasurer and one of the individuals approved by the Board of Trustees. The funds, books, and vouchers and the Treasurer's control shall be at all times subject to the verification and inspection by the Board of Trustees. The Treasurer shall ensure that an audit of the books by an accounting firm approved by the Board of Trustees be performed on an annual basis and also upon a significant change of Association staff. The Treasurer shall ensure that all required tax returns and other governmental requirements be performed in a timely manner. The Treasurer shall chair the Budget and Finance Committee, which is responsible for drafting an annual budget to present to the Board of Trustees.

G. Bonding

A fidelity bond may be purchased for any officer, Trustee, or employee of the Association and in such an amount as the Board of Trustees shall establish.

Article IV. Election Process

A. Nominations

The Nominating Committee shall be responsible for the selection and submission to the Board of Trustees the names of candidates for the offices of the Association as set forth in Article III, section 1 and Article IV, section 1 of these Bylaws.

B. Slate Approval

After presentation to the Board of Trustees, the slate of candidates shall be presented to the House of Delegates for final approval. Further nominations for each office may be made by the House of Delegates.

C. Voting

A vote of the Association members shall be initiated within 60 days after the nominations have been approved by the House of Delegates. The nominee for each position receiving the highest vote, as certified by a Canvassing Committee, shall be declared duly elected. In the event of a tie vote, a supplemental mail ballot election shall be held.

Article V. Executive Director and Staff

A. Executive Director

The administration and management of the Association shall be conducted by an Executive Director, employed or appointed by, and directly responsible to the Board of Trustees.

The Executive Director shall be the chief executive and operating officer of the Association, with responsibility for the management and direction of all operations, programs, activities, and affairs of the Association within the framework of the policies and directives determined by the Board of Trustees. The Executive Director shall be responsible for the employment, annual performance evaluation, and the termination of employment of Association office personnel. The Executive Director shall: serve as the Secretary to the House of Delegates, give notice of and attend all meetings of the Association, keep a record of all proceedings, and have other such duties as may be established by the Board of Trustees.

B. Office Staff

The Association shall employ an office staff to perform and conduct the daily activities of the Association. The staff shall be supervised, directed by and answer to the Executive Director within the framework of accepted office practices and policies established by the Board of Trustees.

Article VI. House of Delegates (House)

A. Composition

The House of Delegates shall consist of the officers of the House of Delegates and any member in good standing upon petition to the Speaker of the House and certification by the Secretary. Prospective delegates must petition the Speaker by a time designated by the Secretary.

B. Ex-Officio Delegates

The Officers, trustees, past presidents of the Maryland Pharmacists Association, and the Officers of the House shall be eligible to serve as Ex-Officio Delegates with vote in the House of Delegates.

C. Officers of the House of Delegates
The Officers of the House of Delegates shall consist of the Speaker, Vice Speaker (who shall be the Speaker-elect), and the Secretary. The Executive Director of the Maryland Pharmacists Association shall serve as Secretary but shall not be entitled to a vote.

D. General Duties of the House Officers
The Officers of the House of Delegates shall arrange the programs for all meetings of the House of Delegates. The Officers shall represent the House of Delegates to the Board of Trustees and Association Committees to ensure the dissemination of information and implementation of policies adopted by the House.

E. Duties of the Speaker of the House
The Speaker of the House shall preside at all meetings of the House of Delegates, unless unavailable at which time the Vice Speaker shall preside. In the event that both the Speaker and the Vice Speaker are unable to preside, the Secretary of the House shall conduct an election for a temporary Speaker for the corresponding meeting of the House of Delegates. The Speaker shall appoint a parliamentarian to serve as an advisor on procedures and rulings. The Speaker shall appoint a House Nominating Committee, a Resolutions Committee, a Constitution and Bylaws Committee (as necessary) and other committees of the House as may be necessary. The Speaker shall present an annual report to the House of Delegates to include action taken on the previous year's resolutions. The term of office for the Speaker is one year.

F. Duties of the Vice Speaker of the House
The Vice Speaker shall be the Speaker-elect, and preside at meetings of the House of Delegates when the Speaker is unavailable, and assume the duties of the Speaker in the event that the Speaker cannot fulfill the duties of that office. The Vice Speaker shall serve as chair of the Resolutions Committee. The term of office for the Vice Speaker is one year. Upon completion of his/her term of office, the Vice Speaker shall automatically assume the office of Speaker of the House.

G. Duties of the Secretary of the House
The Secretary of the House shall read all relevant communications to the House. The Secretary shall conduct and record voting in the House of Delegates when requested by the Speaker. The Secretary shall notify members of the House of Delegates of their appointment and shall report and certify the credentials of all delegates for House of Delegates sessions. The Secretary shall be responsible for the publication and maintenance of proceedings of the House of Delegates and shall distribute relevant reports to the Delegates.

H. Meetings of the House
The House of Delegates shall meet at least twice yearly: once at the Annual Meeting and once at the Mid-Year Meeting. Special meetings of the House may be called at the discretion of the Speaker or upon written request of 10% of the membership of the Association. Each Delegate shall be entitled to one vote. No Delegate shall act as a proxy for another Delegate. All Association members may attend any session of the House of Delegates and shall be granted the privileges of the floor, but only certified delegates may vote.

I. Quorum
A quorum for purposes of conducting the business of the House shall be at least twenty-five (25) Delegates.

J. Resolutions Committee
Resolutions may be submitted to the Resolutions Committee any time prior to the last meeting of the Committee which precedes the Annual Meeting. In addition, resolutions bearing the signature of two active members may be presented to the Speaker or the Secretary of the House of Delegates at least 24 hours prior to consideration by the House.
The Resolutions Committee shall be appointed by the Speaker of the House of Delegates at least ninety (90) days prior to the Annual Meeting of the Association. In the absence or incapacity of the Vice Speaker, a member appointed by the Speaker of the House shall serve as chair of the Resolutions Committee.
The Resolutions Committee shall submit all resolutions to the Board of Trustees at the meeting scheduled in the month prior to the Annual Meeting. The Board of Trustees shall review each resolution and make a recommendation that the House of Delegates adopt, defeat, or refer to a committee.

K. Election of the Speaker and Vice Speaker of the House
The House Nominating Committee shall be responsible for the nomination of candidates for the office of Vice Speaker of the House of Delegates. The office of Speaker of the House of Delegates is automatically filled by the current Vice Speaker. In the event that the Vice Speaker is unable to serve as Speaker, the House Nominating Committee shall be responsible for nomination of candidates for the office of Speaker of the House of Delegates.
The House Nominating Committee will present a slate of at least two candidates (if possible) for each position to a session of the House of Delegates at the Annual Meeting. The House Nominating Committee shall consider experience and demonstrated leadership abilities. Members of the House Nominating Committee may not be nominated for any position.
If approved by the House, an election shall be held at the final session of the House of Delegates at which time the new Officers of the House of Delegates shall be installed.

Article VII. Committees

A. Presidential Appointments
The President shall annually appoint the chair of each committee as may be required by the Constitution or Bylaws or as the President may find necessary.

B. Nominating Committee
The Vice President shall serve as chair of the Nominating Committee. The Nominating Committee shall nominate at least two (2) individuals (if possible) for each forthcoming available seat on the Board of Trustees and the office of Vice President, and Treasurer (on alternate years). The Nominating Committee shall consider geographic diversity, practice specialty, and experience in making its nominations. Nominees for the offices of Vice President and Treasurer shall have a minimum of 2 years MPhA Board of Trustees experience. The slate of candidates shall be presented to the House of Delegates at the Mid-Year meeting.
Members of the Nominating Committee may not be nominated for any position.

C. Budget and Finance Committee
The Treasurer shall serve as the chair of the Budget and Finance Committee. A proposed annual budget of the Association shall be prepared by the Budget and Finance Committee and presented to the Board of Trustees for its approval at least two (2) months prior to the beginning of the fiscal year.

D. Past Presidents' Council
The Past Presidents' Council shall be comprised of all past presidents who are current members. The Past Presidents' Council shall be responsible for the selection of the Honorary President as well as the recipients of all MPhA awards. Selection shall be by a majority vote of at least a minimum of 50% of the Past Presidents responding within 30 days to a notice for a meeting of the Past Presidents' Council. The President may designate additional responsibilities to the Past Presidents' Council as directed by the Board of Trustees. The Past Presidents' Council shall be chaired by the most recent past president not currently serving on the Board of Trustees.

Article VIII. Non-Discrimination Policy
It is the policy of the Maryland Pharmacists Association to prohibit discrimination among individuals on the basis of sex, race, religion, national origin, sexual orientation, age, or physical or mental disability.

Article IX. Amendment of Bylaws
Every proposal to amend these Bylaws must be submitted in writing to the Constitution and Bylaws Committee. After prudent consideration, the committee shall present its recommended changes to the Board of Trustees. The proposed changes shall be presented to the membership at a regular or special meeting of the House of Delegates. Upon the affirmative vote of at least two-thirds of the delegates present at this meeting, a vote of the Association members shall be conducted.
A proposed amendment shall then become part of the Bylaws with an affirmative vote of at least two-thirds of the responders.

Revised 11-17-05

Recognizing Pharmacy Excellence
The 2006 MPhA Awards

Each year, the Maryland Pharmacists Association recognizes professional excellence through a series of awards. To nominate a pharmacist for one of the awards described below, complete the Official Award Nomination Form. The forms should be submitted to: Award Nominations, c/o Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572.

All nominations will be reviewed by the Past Presidents Council who is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the award's presentation at the 124th Annual MPhA Convention.

For consideration, all nominations must be received no later than ***Friday, April 7, 2006.***

- **Pharmacists Mutual Distinguished Young Pharmacist Award**
  Awarded to a pharmacist who graduated within the past ten years and has made a significant contribution to the profession through service to a local, state or national pharmacy organization. ***Who is Eligible:*** Any MPhA pharmacist member who graduated from pharmacy school in 1996 or after.

- **Maryland Pharmacists Association Honorary President**
  An honorary position on the Board of Trustees given to a person, not necessarily a pharmacist, who has worked for the MPhA or Maryland Pharmacy over a long period of time. ***Who is Eligible:*** Any long standing contributor to the profession or the Association.

- **MPhA Mentor Award**
  This award recognizes individuals who encourage pharmacists, technicians, and/or student pharmacists in the pursuit of excellence in education, pharmacy practice, service, and/or advocacy. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the Award.

- **Seidman Distinguished Achievement Award**
  Created to honor the major impact on the pharmacy profession by Henry Seidman, this award is presented for outstanding service by a Maryland pharmacist to the pharmacy profession during *either* the past year or over a period of years. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the award.

- **Wyeth-Ayerst Bowl of Hygeia Award**
  The Bowl of Hygeia recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions. ***Who is Eligible:*** Any MPhA member pharmacist who has not already received the Bowl of Hygeia.

- **Elan Innovative Practice Award**
  Established in 1993, this award aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. Any practicing pharmacist member within the geographic area who has demonstrated innovative pharmacy practice resulting in improved patient care. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the award.

Maryland Pharmacists Association
Award Nomination Form

To nominate a Maryland pharmacist for one of MPhA's annual "Recognizing Pharmacy Excellence" awards, this form must be completed and returned to the Maryland Pharmacists Association no later than ***Friday, April 7, 2006***. All nominations will be held in strictest confidence by the MPhA Past Presidents Council, which is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the presentation of the award.

Please consider the following nominee for:

☐ ***Pharmacist Mutual Distinguished Young Pharmacist Award***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

☐ ***Seidman Distinguished Achievement Award***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

☐ ***Elan Innovative Practice Award***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

☐ ***Wyeth-Ayerst Bowl of Hygeia***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

☐ ***MPhA Mentor Award***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

☐ ***MPhA Honorary President***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

Attach a current resume or curriculum vitae for the nominee that shows their professional and personal achievements. This information is essential for the Past Presidents Council to make its decisions as to which candidates will be recipients of the "Recognizing Pharmacy Excellence" awards. In addition, the nominator should attach a brief letter explaining why the nominee is worthy of receiving this award.

Return the completed form to:

Awards Nominations
c/o Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

Fold

2006 Awards Nominations
Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

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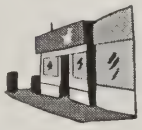

Please call:
Friendly Pharmacy, Int. LLC.
5720 Deale Churchton Road
Deale, Maryland 20751
800-622-3080

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(Continued from page 8)

Pramlintide and insulin should be administered in separate injections and never mixed together, or injected at the same site. Recommended injection sites for pramlintide are the abdomen or thigh; administration in the arm is not recommended due to variable absorption.[8] Because pramlintide slows gastric emptying, absorption of oral medications may be delayed therefore medications intended for rapid onset should be administered at least one hour before or two hours after injecting pramlintide.[8]

Patients taking pramlintide should be encouraged to check their blood glucose several times a day (before and after meals, and at bedtime) and whenever they experience signs or symptoms of hypoglycemia. A healthcare professional should closely monitor blood glucose levels as well as adverse effects to determine the need for dose adjustments of both pramlintide and insulin until the optimal therapeutic regimen is achieved.[2]

The availability of two new therapeutic options to treat diabetes mellitus are very welcome, and provide additional opportunities for pharmacists to educate patients about diabetes management.

Table 1 – Conversion of pramlintide dose to insulin unit equivalents

Dosage Prescribed (mcg)	Increment using a U-100 syringe (units)	Volume (ml)
15	2.5	0.025
30	5.0	0.050
45	7.5	0.075
60	10.0	0.100
120	20.0	0.200

[1] Byetta package insert. San Diego, CA: Amylin Pharmaceuticals, Inc.; 2005, Apr.
[2] Mosby's Drug Consult [Database on the internet]. St. Louis, Missouri: Elsevier Inc. c2005 – [cited 12/14/05]. Available from: http://www.mdconsult.com/das/drug.
[3] Uwaifo GI, Ratner RE. Novel Pharmacologic Agents for Type 2 Diabetes. Endocrinol Metab Clin N Am. 2005;34:155-197.
[4] DeFronzo RA, Ratner RE, Han J, Kim DD, Fineman MS, Baron AD. Effects of exenatide (exendin-4) on glycemic control and weight over 30 weeks in metformin-treated patients with type 2 diabetes. Diabetes Care; 2005 May; 28(5):1092-1100.
[5] Buse JB, Henry RR, Han J, Kim DD, Fineman MS, Baron AD. Effects of exenatide (exendin-4) on glycemic control over 30 weeks in sulfonylurea-treated patients with type 2 diabetes. Diabetes Care; 2004 Nov; 27(11):2628-2635.
[6] Kendall DM, Riddle MC, Rosenstock J, Zhuang D, Kim DD, Fineman MS, Baron AD. Effects of exenatide (exendin-4) on glycemic control over 30 weeks in patients with type 2 diabetes treated with metformin and a sulfonylurea. Diabetes Care; 2005 May; 28(5):1083-1091.
[7] Klasco RK (Ed): DRUGDEX® System (electronic version). Thomson Micromedex, Greenwood Village, Colorado, USA. Available at: http://www.thomsonhc.com (cited: 12/14/05).
[8] Symlin package insert. San Diego, CA: Amylin Pharmaceuticals, Inc.; 2005, Jun.

...edited by Mary Lynn McPherson, Pharm.D., BCPS, CDE
Professor, University of Maryland School of Pharmacy

Rx AND THE LAW

By Rachel Jackson
And Karen E. Peterson, R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

MINORS AND PRESCRIPTIONS: WHERE DOES HIPAA FIT IN?

(Part 2 of 2)

Remember Kate, the pharmacist at Hometown Pharmacy? She was faced with the difficult question of whether or not to give Mrs. Johnson information regarding a prescription her daughter Jenny may have gotten filled recently. Is a minor protected by HIPAA?

State and other applicable laws present three situations when dealing with prescriptions (or any health information) for a minor:

1) When the health care provider must treat the personal representative as the primary decision maker
2) When the health care provider must treat the minor individual as the primary decision maker (the personal representative does not have an absolute right to the information)
3) When the health care provider may treat either the minor or the personal representative as the primary decision maker.

Recall that the first situation happens all the time, when parents are taking care of their baby, toddler, or young child. The third situation is common as the child grows up. Many state pharmacy laws say the 'patient or patient's caregiver' should receive counseling, but do not make the distinction as to when a pharmacist should deal with one over the over.

The second situation is the trickiest, and laws vary from state to state. When is a minor the treatment decision maker? All state laws give minors the power to consent to sexually transmitted infection ("STI") services, although some states add conditions. Some states, such as Massachusetts, also allow a minor to consent to contraceptive services. Since the minor is the one to give consent, he or she is considered the decision maker for this particular treatment; thus any information pertaining to this treatment is considered confidential and the health care provider is not allowed to share it with others, including parents. In this case, HIPAA grants the minor distinct rights that should be respected.

That means the pharmacist should do everything in his or her power to see that the use of certain medications in adolescents are kept confidential. If 15-year-old Sara comes to Hometown Pharmacy with a prescription for Acyclovir 200 mg 5x daily for 10 days, Kate should not discuss it with Sara's mom at the soccer game that weekend. Sara was granted consent by state law, so speaking about it with her mom may be a violation of Sara's rights.

It's true that a minor's confidential information is more prone to 'slip through the cracks' when the information must be shared for payment purposes. Sara could have received confidential STI testing, but the information may show up on her parents' insurance company's Explanation of Benefits

form. Kate shouldn't be the reason Sara's parents find out.

Quite a few studies have shown that minors would not seek STI or contraceptive care if their parents would find out. This is why it is important to know what the laws are in your state, and use your professional judgment when handling prescriptions in these matters. Do your best to keep the information confidential – this will foster a great relationship between you and the patient.

In order to best provide confidentiality to your adolescent patients, there are several things you can do.

- Know your state's laws so you understand when a minor has the right to confidentiality.
- Encourage your minor patients to read all privacy notices to be aware of the rights they may have as an individual.
- If a minor comes in with a new prescription for birth control pills, ask questions during counseling such as, "Upon refill, if your mom is in the store shall I have her pick this up for you?" Then document it!
- Inform the minor that if they use their parents' insurance to cover the cost of the medication, it may show up on a report from the insurance company.
- Ask minor patients if they would like to use an alternate form of communication, such as calling a cell phone or mailing to a friend's house. Then document it!
- Mark confidential prescriptions, using such things as clothespins, stickers, or brightly colored paper.

How should Kate answer Mrs. Johnson's question about Jenny's recent prescription? If it was for acne medication, Mrs. Johnson has a right to know and Kate should answer truthfully; Jenny does not have a right to privacy. If the prescription is for STI treatment, the information is confidential no matter what the state and Kate cannot answer Mrs. Johnson. If the prescription was for birth control, the answer depends on the state. If Hometown Pharmacy is in Massachusetts, Kate should answer that the information is confidential and she can't be of any assistance. However, in Indiana a minor cannot give consent for contraceptive services unless she is married, thus state law would not protect Jenny's information. If Hometown Pharmacy is in Indiana and Jenny managed to get care behind her mother's back, Kate would have to tell Mrs. Johnson the truth unless she suspects the information would endanger Jenny.

Be aware of these three situations. Know your state laws, use your professional judgment, and remember that HIPAA can also apply to minors.

©Rachel Jackson and Karen Peterson. Rachel Jackson is a student at the Iowa College of Pharmacy in Iowa City, Iowa. Karen E. Peterson, R.Ph., J.D. is a Professional Liability Claims Attorney at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

For more information, see:

Boonstra H and Nash E. Minors and the right to consent to health care, *The Guttmacher Report on Public Policy*, 2000, 3(4):4–8. http://www.guttmacher.org/pubs/tgr/03/4/gr030404.pdf.

HIPAA Regulations. http://aspe.hhs.gov/admnsimp/pl104191.htm.

OCR Guidance Explaining Significant Aspects of the Privacy Rule – 4 Dec 2002. http://www.hhs.gov/ocr/hipaa/guidelines/personalrepresentatives.pdf.

Rebecca Gudeman. Adolescent Confidentiality and Privacy Under the Health Insurance Portability and Accountability Act. *Youth Law News: Journal of the National Center of Youth Law*. Jul-Sept 2003. http://www.youthlaw.org/downloads/adolescnt_confidentiality.pdf.

The American Bar Association. Facts about Children and the Law. 28 Dec 2000. http://www.abanet.org/media/factbooks/childlaw.pdf.

The Guttmacher Institute. Minors' Access to STD Services. *State Policies in Brief*. 1 Sept 2005. http://www.guttmacher.org/statecenter/spibs/spib_MASS.pdf.

The Guttmacher Institute. Minors' Access to Contraceptive Services. *State Policies in Brief*. 1 Sept 2005. http://www.guttmacher.org/statecenter/spibs/spib_MACS.pdf.

Continuing Education for Pharmacists

Volume XXIII, No. 9

Recommendations for Prevention and Control of Influenza: 2005-06 Flu Season

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goals. The goal of this lesson is to examine updated recommendations for the prevention and control of influenza for the 2005-06 flu season. The focus is on inactivated influenza vaccine.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. identify etiologic and pathophysiologic characteristics of the influenza viruses;
2. describe the major strategy for prevention of influenza infection;
3. recognize primary changes and updates from previous recommendations for prevention and control of influenza; and
4. recommend sources of information regarding availability and other immunization product issues relative to influenza vaccine for the 2005-06 flu season.

Gossel

Wuest

Epidemics of influenza cause approximately 36,000 deaths each year in the U.S. and are responsible for more than 200,000 hospitalizations annually. Influenza is a contagious respiratory illness caused by influenza viruses that can cause mild to severe illness, and at times can lead to death. Influenza is usually spread person to person through coughing or sneezing of infected persons. Influenza viruses are constantly changing. Rates of influenza infection are highest among children; rates of serious illness and death are greatest among persons aged ≥65 years, children less than two years, and individuals of any age who suffer from medical conditions that place them at increased risk for complications from influenza.

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) has updated its annual recommendations for the use of influenza vaccine during the 2005-06 flu season (*MMWR* 2005; 54:1-40) Four points of interest to pharmacists at the community level include:

- persons with any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration should be vaccinated against influenza;
- all healthcare workers should be vaccinated against influenza annually, and facilities that employ healthcare workers should be strongly encouraged to provide vaccine to workers by using approaches that maximize immunization rates;
- use of both available vaccines (inactivated; and live, attenuated influenza vaccine [LAIV]) is encouraged for eligible persons every influenza season, especially persons in recommended target groups. During periods when inactivated vaccine is in short supply, use of LAIV is especially encouraged when feasible for eligible persons (including healthcare workers) because this might considerably increase the availability of inactivated vaccine for persons in groups at high risk; and
- CDC and other agencies will assess the vaccine supply throughout the manufacturing period and will make recommendations preceding the 2005-06 influenza season regarding the need for tiered timing of vaccination of different risk groups. In addition, CDC will publish ACIP recommendations regarding inactivated vaccine subprioritization (tiering) on a later date in *MMWR*.

Influenza Viruses

Influenza viruses are the most important pathogens that cause acute respiratory disease, largely because of the enormous number of persons affected each year. During the influenza epidemic in the winter of 1962-63, an estimated 80 million persons were affected in the U.S., and deaths from influenza and pneumonia increased by about 70,000. The most severe influenza pandemic (worldwide epidemic) occurred in 1917-18, when up to 20 million persons died.

Epidemiology. Affected persons are the only important source of influenza virus. The virus can be detected in respiratory secretions during the first few days of illness, but is rarely found beyond the first week. Persistent carriers

Table 1
Is it a Cold or Influenza?

Symptom	Cold	Influenza
fever	rare	characteristic high, 102-104°F sudden onset, lasts 3-4 days
headache	rare	prominent
general aches & pains	slight	usual, often severe
fatigue & weakness	mild	extreme, can last 2-3 weeks
prostration	never	early and prominent
runny, stuffy nose	common	sometimes
sneezing	usual	sometimes
sore throat	common	sometimes
chest discomfort, cough	mild to moderate, hacking cough	common, can become severe
complications	sinus congestion, earache	bronchitis, pneumonia; can be life threatening

have not been identified, although there is convincing evidence that mild infections are more common than clinical disease. The viruses may, therefore, persist in a population by causing sporadic mild illness that resembles the common cold.

The antigenic composition of influenza virus vaccine from year to year is determined prior to the beginning of the season by the predominant circulating strains worldwide and may change on a yearly basis. Since 1977, influenza A (H1N1) viruses, influenza A (H3N2) viruses, and influenza B viruses have been in global circulation. In 2001, influenza A (H1N2) viruses emerged.

At any given time, a single subtype of influenza virus A predominates throughout the world. The virus is subject to mutation by a phenomenon known as *antigenic drift* (i.e., single-base mutations leading to single amino acid substitutions) and *antigenic shift* (i.e., a major change in the viral hemagglutinin to a completely new type), resulting in formation of different influenza strains. Influenza B is less likely to mutate.

Type A influenza strains are responsible for major influenza epidemics. Nearly all epidemics reach their peak during the winter, with January and February reporting the greatest number of cases in the northern hemisphere. Type B influenza virus infects children primarily, and is often localized to schools and other closed populations. Type B influenza virus typically causes less severe epidemics and occurs in four-to six-year cycles.

Epidemics in any single locality tend to persist for only six to eight weeks. The short, explosive nature of the epidemics is accounted for by the short incubation period (two to three days), ease of transmission, widespread seeding of the virus prior to the outbreak, and the high attack rates.

Clinical Presentation. The clinical manifestations of influenza may range from symptoms of mild upper respiratory illness to severe pneumonia with involvement of numerous organs. It is often difficult to distinguish the illness of isolated cases from that caused by other common upper respiratory tract pathogens such as the common cold (Table 1). Oftentimes, a characteristic pattern is readily discernible when groups of affected individuals are encountered (e.g., an epidemic).

Following an incubation period of two to three days, the patient presents with the characteristic syndrome of sudden onset of prostration (i.e., extreme exhaustion), myalgia (muscle pain), headache, and pain behind the eyes. Fever of 103° to 104° F may occur within a few hours. Bradycardia is the norm, but tachycardia is characteristic of the most severely ill. The face appears flushed and hot, and the skin feels dry.

The first 24 to 48 hours of illness are characterized by systemic symptoms. Respiratory involvement becomes more prominent as the systemic symptoms subside. Pharyngitis alone is unusual, but associations with runny nose, conjunctivitis, nasopharyngitis, and inflamed trachea and bronchi are common. Mucosal edema is always present and may progress to hemorrhagic necrosis of the tracheobronchial mucosa. Rales (abnormal respiratory sounds; "gurgling" noise on breathing) in the lungs are present in up to a third of uncomplicated cases. A dry, hacking cough and burning across the sternum are often the most distressing components of the illness. Gastrointestinal manifestations are rare.

Secondary bacterial infections of the ears, sinus, bronchi, and lungs may appear during the late stages of illness, and are noted by a sudden return of high fever and extreme exhaustion or shortness of breath. Bacterial pneumonia is responsible for the majority of fatalities. Bacterial infections that manifest on day three to five of influenza are especially problematic in patients with congestive heart failure, rheumatic heart disease, or chronic pulmonary disease, and in pregnant women. The disease tends to be more severe in such patients.

Patients usually recover in a few days to, at most, a week. Those convalescing longer may exhibit persistent cough, easy fatigability, muscle aching, or malaise. Symptoms persisting beyond three weeks can often be associated with depression.

Controlling Influenza

The primary option for controlling influenza is immunoprophylaxis with vaccine. Inactivated (i.e., killed virus) influenza vaccine and live, attenuated influenza vaccine (LAIV) are available for use in the U.S. Annual vaccination of persons at high risk for complications and their contacts is the most

effective means for reducing influenza morbidity. Increased vaccination rates among persons residing or working in closed settings (e.g., nursing homes, dormitories) can reduce the onset of outbreaks. Vaccination of healthcare workers and others in close contact with persons at increased risk for severe influenza illness can also reduce transmission of influenza virus and subsequent influenza-related complications. Antiviral drugs used for chemoprophylaxis or treatment of influenza are important adjuncts to the vaccine; however, they are not a substitute for vaccination.

Target Groups for Vaccination. Vaccination with inactivated influenza vaccine is recommended for the following persons who are at increased risk for complications from influenza:

- persons aged ≥65 years;
- residents of nursing homes and other chronic-care facilities that house persons of any age who have chronic medical conditions;
- adults and children who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus);
- adults and children who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration;
- children and adolescents (aged six months to 18 years) who are receiving long-term aspirin therapy and, therefore, might be at risk for experiencing Reye syndrome after influenza infection;
- women who will be pregnant during the influenza season; and
- children aged six to 23 months.

Table 2
Influenza Vaccine Comparisons

Factor	Inactivated Vaccine	Live, Attenuated Vaccine (LAIV)
route of administration	IM injection	intranasal spray
type of vaccine	killed virus	live virus
number of strains	3 (2 Influenza A and 1 Influenza B)	same as inactivated
strains updated	annually	same as inactivated
administration frequency	annually	same as inactivated
approved age and risk groups	≥6 months	healthy persons 5-49 years
administered to close contacts of immunosuppressed not requiring protected environment	yes	yes
administered to close contacts of immunosuppressed requiring protected environment	yes	inactivated vaccine preferred
administered to close contacts of persons at high risk, but not severely immunosuppressed	yes	yes
administered simultaneously with other vaccines	yes*	yes**
administered within 4 weeks of another live vaccine	yes	best to space 4 weeks apart
administered within 4 weeks of inactivated vaccine	yes	yes

*Inactivated influenza vaccine coadministration has been evaluated systematically only among adults with pneumococcal polysaccharide vaccine.
**No data available on safety or efficacy

Vaccination is also recommended for:

- persons aged 50 to 64 years because this group has an increased prevalence of high-risk conditions (as identified above);
- persons who can transmit influenza to those at high risk (e.g., employees of assisted living and other residences for persons in groups at high risk);
- healthcare workers; and
- travelers to the tropics or those who travel with organized tourist groups at any time of year, or persons who travel to the Southern Hemisphere between April and September.

In addition to groups cited above for which annual influenza vaccination is recommended, influenza vaccine should be administered to any person who wishes to reduce the likelihood of becoming ill with influenza or transmitting the infection to others should they become infected. Individuals in essential community service roles (e.g., firemen, police) should be considered for vaccination to minimize disruption of these activities during influenza outbreaks.

Comparison of Live, Attenuated Influenza Vaccine with Inactivated Influenza Vaccine. Both inactivated influenza vaccine and LAIV can reduce the risk for influenza infection and illness. The vaccines are compared in Table 2.

Similarities. Both forms of vaccine contain strains of influenza viruses that are antigenically equivalent to the recommended strains each year: one influenza A (H3N2) virus, one influenza A (H1N1) virus, and one influenza B virus. One or more virus strains may be altered each year based on the results of global surveillance for influenza viruses and emergence and spread of new strains. Viruses for both vaccines are grown in fertilized chicken eggs, thus both vaccines may contain limited amounts of residual egg protein. Both vaccines are administered

Table 3
Approved Influenza Vaccines by Age Groups – U.S.

Vaccine	6 mo-3 yrs	4 yrs	5-49 yrs	≥50 yrs
FluZone® (*Sanofi Pasteur, Inc.*)	X*	X	X	X
Fluvirin™ (*Chiron*)		X	X	X
FluMist™ (*MedImmune, Inc.*)			X	

*Children 6-35 months should receive 0.25 mL/dose. Persons >35 months should receive 0.5 mL/dose.

annually to provide optimal protection against influenza infections.

Differences. Inactivated influenza vaccine contains killed viruses, whereas LAIV contains live, attenuated viruses that remain capable of replication. Inactivated influenza vaccine is administered intramuscularly by injection. LAIV is administered intranasally by sprayer. LAIV is more expensive than inactivated influenza vaccine, although the price differential has decreased substantially over the past year. Inactivated influenza vaccine is approved for use in persons aged ≥6 months, including those who are healthy and those with chronic medical conditions, whereas LAIV is approved for use among healthy persons aged five to 49 years.

Recommended Vaccines and Doses for Different Age Groups. When vaccinating children aged six months to three years, only inactivated influenza vaccine that has been approved by FDA for this age group should be used (Table 3). Inactivated influenza vaccine from Sanofi Pasteur, Inc. (FluZone®) is approved for use among children aged ≥6 months. Inactivated influenza vaccine from Chiron (Fluvirin™) is labeled in the U.S. for use in children aged ≥4 years because data to demonstrate efficacy in younger persons have not been provided to FDA. LAIV from MedImmune (FluMist™) is approved for use in healthy individuals aged five to 49 years.

Timing of Annual Influenza Vaccination. Individuals at high risk for serious complications should be vaccinated beginning in September if vaccine is available. In facilities housing elderly residents (e.g., nursing homes), vaccination before October should generally be avoided because antibody levels in such persons can begin to decrease soon after vaccination, thus leading to insufficient immunity. Children nine years of age and under who have not been previously vaccinated require two doses spaced at least one month apart. They can receive their first dose in September so that both doses of vaccine can be administered before the onset of flu season. Children who have been previously vaccinated require only one dose to provide optimal protection against influenza.

In the U.S., October to November is the optimal time to vaccinate. It is recommended that vaccination be provided in October and earlier primarily in individuals aged ≥50 years, persons <50 years who are at increased risk for influenza-related complications (including children aged six to 23 months), household contacts of children aged 0 to 23 months), and healthcare workers. Vaccination of all other persons should be deferred until November, ideally, unless vaccine supplies dictate otherwise.

Many individuals who should or wish to receive influenza vaccine remain unvaccinated after November. Influenza vaccine should continue to be offered in December, and throughout the influenza season, as long as vaccine supplies remain available, even after influenza activity has been documented in the community. Seasonal influenza activity in the United States can begin to increase as early as October or November, but influenza activity has not reached peak levels in the majority of recent seasons until late December-early March. Although the timing of influenza activity can vary by region, vaccine administered after November is still likely to offer benefit in the majority of influenza seasons. Adults develop peak antibody protection against influenza infection two weeks after vaccination.

Sources of Information Regarding Influenza and Its Surveillance. Information regarding influenza surveillance, prevention, detection, and control is available at www.cdc.gov/flu/weekly/fluactivity.htm. Periodic updates regarding influenza are published in the *Morbidity and Mortality Weekly Report (MMWR)* (www.cdc.gov/mmwr).

A Note on Bird Flu

Popularized by the press during the past year, bird flu (Avian Influenza) is a highly infectious disease of birds caused by the H5N1 subtype of influenza A virus. This virus circulates among birds worldwide and can be deadly to them. A few human deaths have been reported worldwide. The World Health Organization is continuing to monitor antigenic and genetic changes in circulating H5N1 viruses, especially in humans.

Continuing Education Quiz

This month's questions are taken from the article on "Recommendations for Prevention and Control of Influenza: 2005-06 Flu Season". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 9/15/08. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-05-009-H01.

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The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education for pharmacists.

1. The letter "L" in LAIV refers to which of the following?
   a. Lasting
   b. Latent
   c. Live
   d. Lymphatic

2. The most severe influenza pandemic, when up to 20 million people died, occurred in:
   a. 1897 to 1898.
   b. 1917 to 1918.
   c. 1962 to 1963.
   d. 1992 to 1993.

3. In persons affected by the influenza virus, the virus is most likely to be detected in respiratory secretions during:
   a. the first few days.
   b. days 4 to 6.
   c. days 7 to 9.
   d. days 11 to 14.

4. From Table 1, the symptom more likely to be present with influenza infection than the common cold is:
   a. sneezing.
   b. runny, stuffy nose.
   c. sore throat.
   d. high fever.

5. When the influenza virus mutates by undergoing a single-based mutation leading to a single amino acid substitution in its DNA strand, it is referred to as an:
   a. antibody shift.
   b. antibody drift.
   c. antigenic shift.
   d. antigenic drift.

6. The form of influenza virus that is LESS likely to mutate is:
   a. Influenza A.
   b. Influenza B.

7. Which of the following is responsible for the majority of fatalities in patients with influenza?
   a. Bacterial pneumonia
   b. Heart failure
   c. Hypertensive crisis
   d. Pulmonary edema

8. Both forms of influenza vaccine contain strains of viruses in which of the following ratios?
   a. One influenza A virus and one influenza B virus
   b. One influenza A virus and two influenza B viruses
   c. Two influenza A viruses and one influenza B virus
   d. Two influenza A viruses and two influenza B viruses

9. Inactivated influenza vaccine (FluZone®) is approved for use among children as young as:
   a. one month.
   b. three months.
   c. six months.

10. The optimal time for an annual influenza vaccine is:
   a. August.
   b. October.
   c. December.
   d. February.

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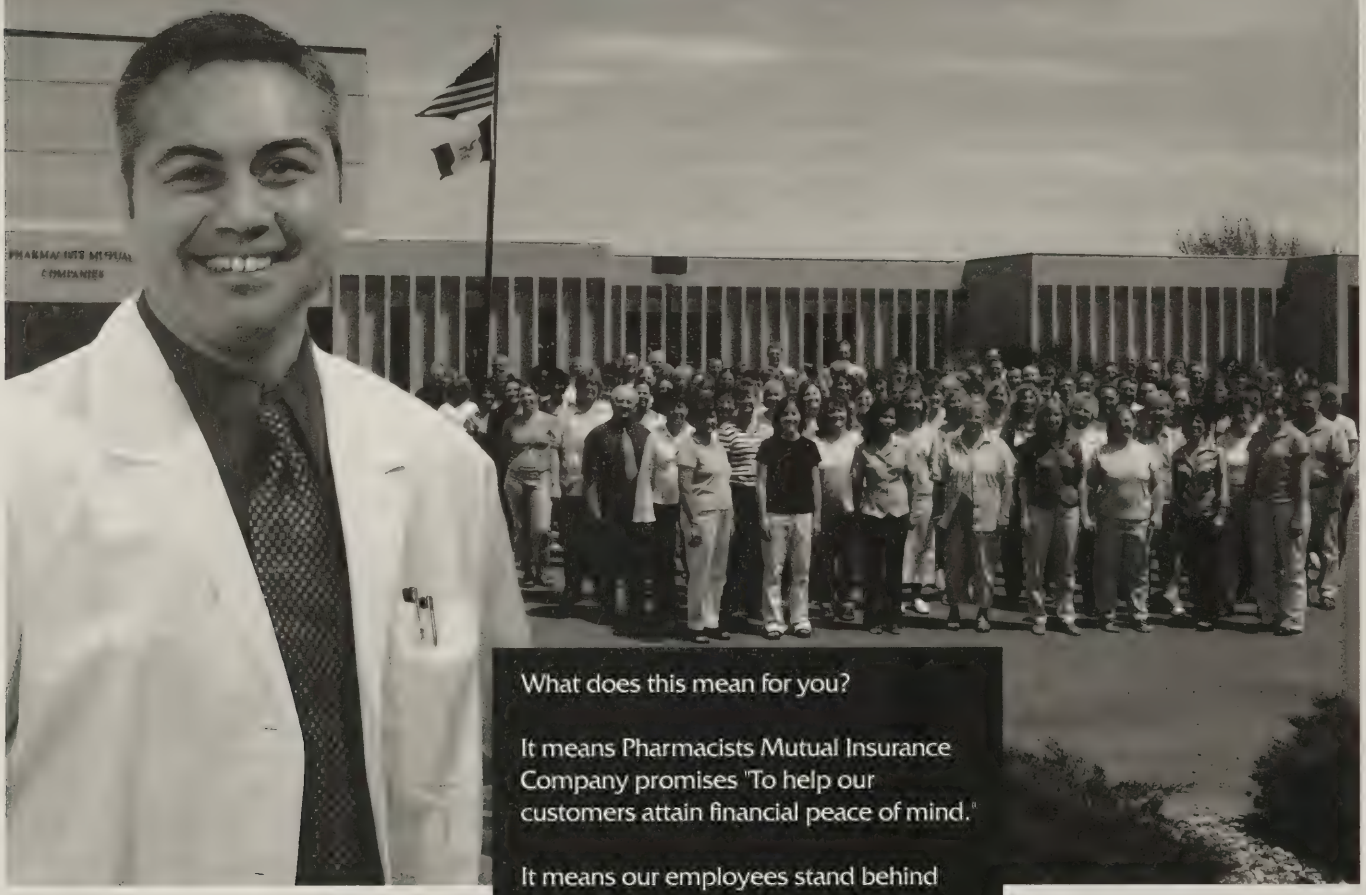

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Maryland Pharmacist

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"Matthew Shimoda, Pharm.D."

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"In Pictures"

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"Chemotherapy Update: Oral Tyrosine Kinase Inhibitors"

Continuing Education
"Natural Products: Calcium to Capsicum"

MARYLAND PHARMACISTS ASSOCIATION

APRIL/MAY/JUNE 2006

Maryland Pharmacists Association

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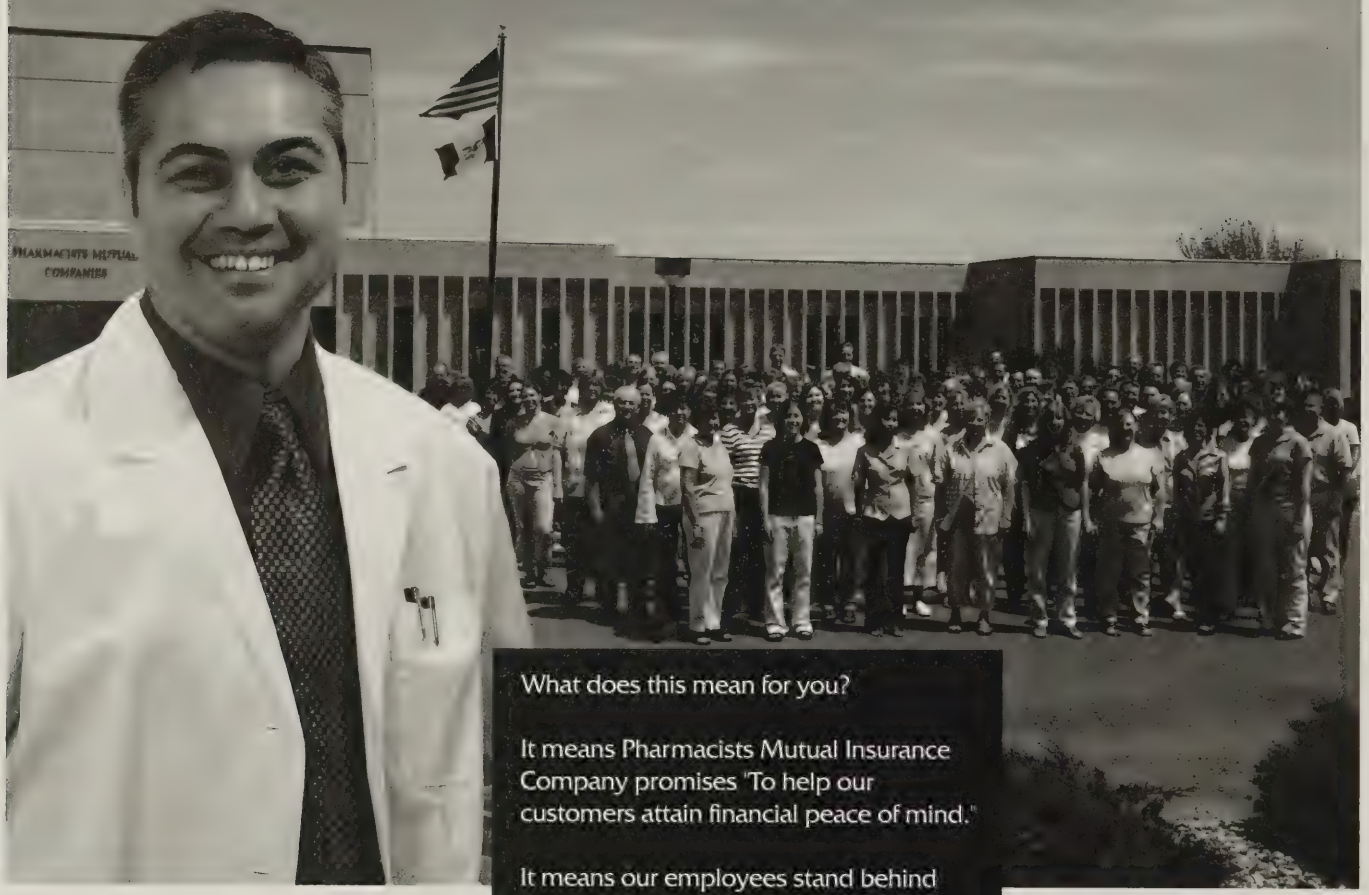

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From the President

Matthew Shimoda, Pharm.D.

First and foremost I would like to personally thank the Officers, Board of Trustees, Executive Director Howard Schiff, and especially our office staff Elsie and Nancy. Without this infrastructure this organization would not be able to function for the good of our current and future members.

This has been a trying yet productive year for the profession of Pharmacy. We have endured national catastrophic disasters that showed the country that Pharmacists can and will do "what ever it takes" to care for our patients. Many of our members were at the forefront in this effort and for that I Thank You. I know that I have talked about the beginning, and continuing process that our Profession faced with regards to Medicare Part D and we are all probably tired about hearing about it again, but this has truly been an historic event for Pharmacy. We all suffered through the confusion and pain that this program brought to our practices, but in the end we as Pharmacists are the "Heroes" that made this program even come close to being a success. I can't pick-up any one of the Journals dealing with Pharmacy and see the same pained expressions and complaints about the Medicare Modernization Act of 2003, yet we have made a difference for millions of recipients in our state as well as the country for that we should feel proud.

This year has been as equally busy for MPhA on the Legislative front. Many important issues affecting our daily practices came before and were debated in the United States Congress as well as our own State Legislation. The Technician issue, Pseudoephedrine mandates, Electronic Prescribing, budgetary issues concerning the building of the Pharmacy School addition (once and for all!), Prescription drug monitoring programs, establishment of a clear contraception dispensing program authorizing Pharmacists to dispense without a prescription, the "day after pill" and how this will affect individual Pharmacists and Pharmacies. These are only some of the issues the Profession faces. Our association has been active in keeping our membership informed and in many cases able to testify about these important issues to our elected officials. This is in many ways is thanks to the Maryland Pharmacy Coalition, Howard, and especially Muhl Flowers who will be sorely missed as the liaison and Chair of our Legislative Committee. Thank you for your dedication and hard work over these many years. As you can see the MPhA is busy with the ongoing issues effecting Pharmacy and we will continue to be the "watch dog" with these and I am sure many more issues to come.

This April, I had the privilege to attend the Annual APhA Convention in San Francisco with Cynthia, Howard, and Ginger. It was exciting to see many old friends of Pharmacy and hear about the current state of affairs facing all of us. I will tell you that we in Maryland are not alone in the daunting task of running a Pharmacists Association! I had the opportunity to network and glean ideas from our fellow colleagues across the country. Soon to be President Ginger Apyar has been very active in attending Leadership conferences, meetings, and having the enthusiasm to want to make MPhA a more efficient and effective conduit for our profession. Thank You Ginger for going that extra mile for everyone.

When Cynthia Boyle became President of the Association she set forth worthy goals that would lead us forward. These goals were not meant to be accomplished in a day, or in her term as President. The goals she set forth have been and will continue to evolve and as an Association we need to see that the basic premise of these goals is not lost.

I want to thank the members of all our committees for their hard and more importantly innovative ideas. I thought that it was important to focus on all of the goals yet concentrate on a few at a time to allow for more continuity as a group. I will list some of the committees as well as goals to give some clarity for the future.

Membership

- This is one of the toughest challenges we face. This is certainly not unique to our Association and as a matter of fact we are doing much better than many of our counterparts.
- Adding a Technician category was a priority of mine especially with upcoming regulatory issues. We have many Technicians that have joined and many more inquires.
- At the suggestion of the committee and Elsie we have sent out mass mailings to Pharmacists that may have just forgotten to renew or even better see THE VALUE of joining our organization, this was a success with many additions.
- We have stressed the value of personal contact with our fellow Pharmacists/Technicians to encourage them to join.
- We have accomplished our goal of enrolling all facets of practice settings with the help of our diverse Board.

Communications

- The Web site has been greatly enhanced, but we still need to allow for more individual member sites.
- We now have a new Logo (looks great-thanks Butch).
- Electronic payment has been activated.
- We still need to explore the possibility of e-communities with members being allowed to explore the many questions that we all face in our daily practices.
- We need to consider our monthly newsletter being sent via e-mail.

Convention/Meetings

- As with this year's Annual Convention the theme "All Shook-up" will be the case. We are trying new formats just like other State and National Pharmacy organizations.
- We will see how this new format works and possibly look to other formats in the future.
- It has been a difficult year finding funding for the CE's as grant money must be used and it MUST be requested as early as possible to allow the Association time to ascertain new topics and speakers.
- The Association has been fortunate to provide quality CE's due to the hard work of the committee and staff.

MPhA Foundation

- We need a clear and concise definition of what the Foundation needs from the Association
- As discussed by the Executive Committee we need some guidance as to an updated goal.

There are many more goals and needs for the Association and with the continued hard work of everyone we can achieve an Association that people want to be a part of.

Many more Thanks need to go out. Thank You Mark Sanford for your help with the new Constitution and Bylaws committee and the tedious job in having one ready to be voted on and passed. To our ASP Board member Lisa Clayville you always added solid comments from the students as their advocate. You will be sorely missed. Dean Knapp, Thank you for giving so much assistance from the UMB School of Pharmacy and your wisdom to our Board.

It has been a great year and I know in my heart it will be even better next year. I will still put in my plea that with the help of many no task seems as big.

Once again, many thanks to the Association and its members. 2006–2007 will bring bigger and better things for all of our members.

Thanks to all,
Matthew Shimoda, PharmD
President 2005 - 2006
Maryland Pharmacists Association

MPhA 124th Annual Convention In Pictures
Ocean City, Maryland
June 10 - 13, 2006

Matt, Ginger, & Joe

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Trade Show

Crab Feast
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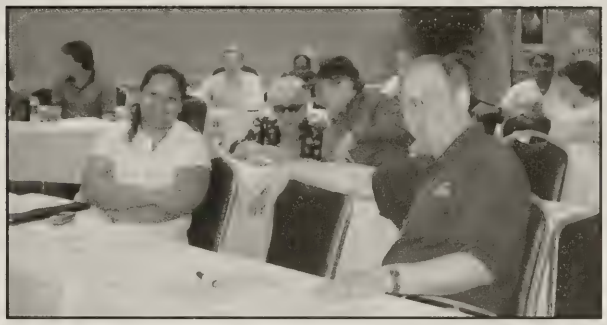

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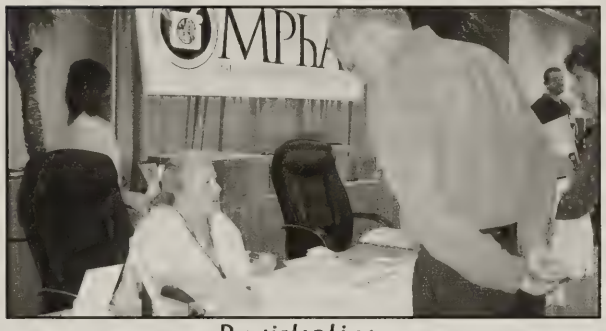

Registration
Elsie and the Leary's

Fred

Matt and Cynthia

Joe and Sam

Therapeutically Speaking...

Chemotherapy Update: Oral Tyrosine Kinase Inhibitors

Deborah M. McNutt, Pharm.D and James A. Trovato, Pharm.D. BCOP

Over the past ten years, the treatment of cancer has evolved tremendously. Greater understanding cancer cell biology has led to the development of a new generation of chemotherapeutic agents such as monoclonal antibodies and kinase inhibitors.[1, 2] Although the majority of these targeted chemotherapeutic agents are administered intravenously, recently approved tyrosine kinase inhibitors are oral medications. This update will focus on the mechanism of action, indications, pharmacokinetics, adverse effects, and key patient counseling information for the newer oral tyrosine kinase inhibitors ***erlotinib*** *(Tarceva),* ***sorafenib*** *(Nexavar), and* ***sunitinib*** *(Sutent). Additionally, safety issues regarding the storage, handling, and dispensing of these agents will be discussed.*

Oral Tyrosine Kinase Inhibitors

The oral tyrosine kinase inhibitors are a growing class of chemotherapeutic agents that community pharmacists will increasingly encounter. The mechanism of action of these agents may be responsible for their tolerable and unique side effect profile. Simply stated, the tyrosine kinase inhibitors, erlotinib, sorafenib, and sunitinib act intracellularly by binding to the tyrosine kinase domain of the growth factor receptor. This in turn prevents the activation of many signaling pathways within the cancer cell responsible for promoting tumor growth, metastasis, and angiogenesis (new blood vessel formation). Erlotinib is an inhibitor of the human epidermal growth factor receptor type 1 tyrosine kinase, whereas sorafenib and sunitinib inhibit multiple receptor kinases including the vascular endothelial growth factor (VEGF) tyrosine kinase.

Erlotinib (Tarceva®) is FDA approved as monotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have failed at least one chemotherapy regimen. It is also indicated in combination therapy with gemcitabine for the first-line treatment of locally advanced, unresectable or metastatic pancreatic cancer.[3] The recommended daily dose of erlotinib is 150 mg daily, which is approximately 60% absorbed without food and increases to almost 100% with food.[3] Despite the greater bioavailability with food, it is recommended to take erlotinib one hour before or two hours after meals. There is no data on dosage adjustment for liver dysfunction or renal impairment.

Erlotinib is 93% protein bound and primarily metabolized by the CYP3A4 enzyme system. Strong CYP3A4 enzyme inducers such as phenytoin, carbamazepine, phenobarbital, and herbal supplements (St. John's Wort) will decrease the concentration of erlotinib. Known CYP3A4 enzyme inhibitors, such as antifungal agents (e.g., ketoconazole, itraconazole), and antiretrovirals (e.g., ritonivir, nelfinavir) and will significantly increase erlotinib concentration, necessitating dosage adjustment.[3] In addition, patients taking warfarin should be monitored for bleeding.

The most common adverse events associated with therapy are an acne-like rash, dry skin, diarrhea, conjunctivitis, and dry eyes, which can be symptomatically managed.[4, 5] Rash is best described as a pustular/papular eruption with an acne-like distribution. Systemic and topical retinoids used to treat acne vulgaris are not recommended; clindamycin 1% gel or clindamycin 1% with benzoyl peroxide 5% gel have been shown to be effective. Dry skin can be treated with emollients such as Eucerin or Aquaphor. Although rare, interstitial lung disease has been reported and the onset has ranged from 6 days to 9 months after the initiation of therapy.[5]

Patient counseling points include taking erlotinib on an empty stomach, and self-monitoring for adverse effects (e.g., acne-like rash, dry skin, dry eyes). Should these effects, persistent diarrhea, nausea, vomiting, eye irritation, unexplained shortness of breath or cough occur, the patient should contact their physician immediately. Patients who are taking warfarin concurrently should self-monitor for bleeding or unexplained bruising, and contact their prescriber if such occurs.

Sunitinib (Sutent®) is FDA approved for the treatment of gastrointestinal stromal tumor after disease progression and for the treatment of advanced renal cell carcinoma [6]. The daily-recommended dose is 50 mg for four weeks, then two weeks off. [6] Food has no effect on the bioavailability of sunitinib and it is 90% – 95% protein bound. Like erlotinib, the CYP3A4 enzymes are the primary metabolizers of sunitinib, and co-administration with known CYP3A4 inducers and inhibitors may necessitate dosage adjustment.[6] Grapefruit juice may increase plasma concentrations of sunitinib.[6]

There is no data on dosage adjustment for liver dysfunction or renal impairment.

The most common are adverse events associated with sunitinib are fatigue, gastrointestinal complaints (nausea, vomiting, diarrhea, constipation, abdominal pain), mucositis/stomatitis, bleeding, neutropenia, muscle pain, and anorexia.[7-9] In addition, adverse events that may affect the patient psychosocially are rash, skin and hair discoloration, and hand-foot syndrome.[7-9]

Patient counseling points include administration without regard to food, common adverse effects (e.g., diarrhea, nausea, mouth pain/irritation, dyspepsia, vomiting, dysgeusia, fatigue and hypertension), and possible need for supportive care (e.g., anti-emetic or anti-diarrheal medication). Patients should be told to self-monitor for yellow skin discoloration that may occur after a week of therapy, and depigmentation of hair (e.g., gray color). Other dermatologic effects include dryness, thickening or cracking of skin, and blister or rash formation on palms of hand and soles of feet.

Sorafenib (Nexavar®) is FDA approved for the treatment of patients with advanced renal cell carcinoma (RCC).[10] In a Phase III trial sorafenib significantly prolonged the progression-free survival compared with placebo in patients with previously treated advanced RCC.[11] In addition, 74% of sorafenib patients had tumor shrinkage as compared to 20% of placebo patients.

The oral bioavailability of sorafenib is 38-49% and this is substantially reduced when taken with a high-fat meal; sorafenib should be taken on an empty stomach.[10] The recommended daily dose of sorafenib is 400 mg (2 x 200 mg tablets) taken twice daily. If patients experience intolerable side effects then the drug should be stopped and/or dose reduced. When dose reduction is necessary, reduce to 400 mg once daily or every other day if necessary.

Sorafenib is metabolized primarily in the liver, although dosage adjustment is not necessary with mild to moderate hepatic or renal impairment.[10] Sorafinib has not been evaluated in patients with severe hepatic or renal impairment. Co-administration with ketoconazole did not result in increased sorafenib serum concentrations, therefore sorafenib metabolism is unlikely to be altered by CYP3A4 inhibitors.[10] Although there is no clinical information on the effect of CYP3A4 inducers on the pharmacokinetics of sorafenib, inducers of CYP3A4 activity are expected to increase metabolism of sorafenib.[10] The most common adverse effects associated with sorafenib are rash, diarrhea, hand-foot skin reaction, fatigue, and hypertension.[11]

Patient counseling points include informing female patients that sorafenib may cause birth defects or fetal loss, and pregnancy should be avoided during treatment and for at least 2 weeks after topping therapy. In fact, both men and women should be counseled to use effective birth control, and breast-feeding should be avoided. Patients should be counseled about potential hand-foot skin irritation (e.g., ulceration, blistering or severe pain) and rash; contact prescriber should such occur. Blood pressure should be routinely monitored during therapy, especially during the first six weeks of therapy due to risk of hypertension.

Safe Handling of Oral Chemotherapy

Proper storage recommendations for all oral chemotherapeutic agents include using shelves and storage areas that bear clear and distinctive labeling identifying them as hazardous drugs.[12] Oral chemotherapy should be segregated from all other inventory drugs to reduce potential errors and to ensure the safety of personnel.[12] The risk of handling oral chemotherapy without the use of gloves is unknown, but the American Society of Health-System Pharmacists (ASHP) has put forth recommendations for the compounding and handling of, and reducing exposure to hazardous drugs to help ensure the safety of all pharmacy personnel.[13] The following is an abbreviated list of these ASHP recommendations that pertain to the community pharmacist.

- Hazardous drugs should be labeled or otherwise identified as such to prevent improper handling.
- Tablet and capsule forms of hazardous drugs should not be placed in automated counting machines, which subject them to stress and may introduce powdered contaminants into the work area.
- Workers should be aware that tablets or capsules might be coated with a dust of residual hazardous drug that could be inhaled, absorbed through the skin, ingested, or spread to other locations, and that liquid formulations may be aerosolized or spilled.
- During routine handling of oral hazardous drugs and contaminated equipment, workers should wear two pairs of gloves that meet the ASTM chemotherapy glove standard.
- Wash hands thoroughly after removing gloves.
- Counting and pouring of hazardous drugs should be done carefully, and clean equipment should be dedicated for use with these drugs.
- Hazardous drugs should be dispensed in the final dose and form whenever possible.
- Disposal of unused or unusable oral dosage forms of hazardous drugs should be performed in the same manner as for hazardous injectable forms and waste.

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Edited by….

Mary Lynn McPherson, Pharm.D., BCPS
Professor, University of Maryland, School of Pharmacy

Rx AND THE LAW

By Dena Kroska and Karen E. Peterson, R.Ph, J.D.

*This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.*

COLLABORATIVE PRACTICE: RISKS AND REWARDS

Increasingly, pharmacists are becoming more involved as decision-makers in patient care through collaborative practice agreements with physicians and other practitioners with prescriptive authority. A collaborative practice agreement is defined as a voluntary agreement between a prescriber and pharmacist establishing cooperative practice procedures under defined conditions. The term "collaborative practice" is often used interchangeably with the term "collaborative drug therapy management", which refers to the practice where prescribers authorize pharmacists to engage in specific activities, such as the initiation, adjustment or evaluation of drug therapy.

These collaborative arrangements between prescribers and pharmacists offer many benefits for patients, such as increased access to healthcare through a pharmacist, a reduction in the number drug-related complications due to optimal management of drug therapy, and a decrease in costs. In addition, benefits to prescribers include reduced costs of care, as well as fewer chronic care patient visits, which allows more time to care for acute care patients. Finally, these arrangements allow pharmacists to focus on the patient instead of the product, so they are able to apply their specialized knowledge of drug therapy to improve patient outcomes.

As with any practice opportunity, it is necessary to evaluate the risks, as well as the benefits, before deciding to become involved. However, one factor that makes the risk of engaging in a collaborative practice arrangement difficult to evaluate is that it is difficult to tell what, if any, authority is granted to a pharmacist by a state board of pharmacy to enter into these arrangements. An informal survey of state boards of pharmacy revealed wide variances from state to state, as well as scope of practice rules that are not always easy to interpret. Pharmacists practicing in states where collaborative practice arrangements are neither explicitly allowed, nor explicitly prohibited may consider seeking further clarification from the state board before entering in to such arrangements.

Pharmacists practicing in states where collaborative arrangements are explicitly allowed must be cautious to strictly adhere to the rules and regulations governing the arrangements. Regulations may determine

minimum qualifications of parties to collaborative agreements, set limitations on activities or classes of drugs that are the subject of agreements, or set forth the necessary structure or components of the agreement.

By assuming responsibility of the initiation of drug therapy according to a collaborative arrangement with a prescriber, a pharmacist may assume a greater risk of liability if there is an adverse event. When considering an opportunity to enter in to a collaborative arrangement with a prescriber, it is crucial that both parties thoroughly review the proposed agreement. The agreement will set forth the rights and responsibilities of both parties. It is particularly important that the parties understand how responsibility for adverse outcomes is apportioned. It is wise for both parties to confirm that their activities under such an arrangement are covered by their respective professional liability insurance carriers and for each party to obtain proof of the other's coverage.

Collaborative practice arrangements present some very exciting opportunities for pharmacists to tangibly impact patient care in a positive manner. They may also allow a pharmacist to grow his or her business in a new direction. The opportunities are abundant, but so are the risks. A thorough understanding of both will allow a pharmacist to make wise decisions about his or her role in this evolving area.

References:

©Dena Kroska and Karen Peterson. Dena Kroska is a Pharm. D Candidate at Drake University in Des Moines, Iowa.. Karen E. Peterson, R.Ph., J.D. is a Professional Liability Claims Attorney at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

NPI Update: NCPDP Prepares to Enumerate Authorizing Pharmacies

With the recent CMS publication of their requirements of Electronic File Interchange Organizations (EFIOs) on their web site http://www.cms.hhs.gov/NationalProvIdentStand/ *NCPDP continues to move forward with their enumeration plans for pharmacies. CMS has targeted "late spring" to go live with bulk enumeration for EFIOs and NCPDP is poised to begin enumeration when CMS is ready. NCPDP was selected as a beta test site by CMS and conducted testing with CMS during February 2006.*

What is EFI?

Electronic File Interchange (EFI), also referred to as "bulk enumeration", is a process by which a health care provider (e.g. pharmacy) or group of providers (pharmacies) can have a particular organization (the "EFIO") apply for National Provider Identifiers (NPI) on their behalf. In other words, rather than a pharmacy or group of pharmacies submitting a paper or web NPI application, the EFIO obtains an NPI for them.

How Did NCPDP Decide to Become an EFIO?

Pharmacies are currently the only providers that have a single identifier, the NCPDP Provider (pharmacy) ID, formerly known as the NABP number. The administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (P.L. 104-191) required the Secretary of HHS to adopt a unique identifier for all health care providers, including pharmacies, for use in the nationwide health care system. Between now and May 23, 2007, our industry must move away from using the NCPDP Provider ID on claims and other HIPAA standard transactions to using the pharmacy's new NPI.

For over two decades, NCPDP has been enumerating pharmacies with NCPDP Provider IDs. NCPDP maintains a database of all pharmacies that includes other information on pharmacy demographics and hours of operation, pharmacy payment center information, state license numbers and other affiliations. Industry uses this database for claims processing, direct mailings of product recalls and publications, network development, health plan directories and rebate information. When asked if pharmacies would prefer for NCPDP to bulk enumerate pharmacies and obtain their NPIs, virtually every pharmacy chain supported the idea.

Recent EFIO Activities

As a result, NCPDP enhanced the current database to include information required by CMS when enumerating providers as well as other information not maintained by CMS but important for proper reimbursement. The database is currently in production and the additional data is being added from pharmacies submitting NCPDP's paper application/update forms available at http://www.ncpdp.org/PDF/Provider_number_app.pdf. Also, a standard Excel file format is available to those pharmacy chains that wish to electronically submit information to NCPDP. To obtain the Excel format, please contact Jeannine Deese at jdeese@ncpdp.org. It will also be published on the web site soon.

NCPDP is encouraging pharmacies to cleanse their internal data and update their pharmacy information with NCPDP between now and May so that when CMS is ready to go live with the EFI submission/bulk enumeration in late spring, pharmacy data on the NCPDP database is clean and ready to submit on behalf of those pharmacies that have authorized NCPDP to do so.

What if a Pharmacy has Already Obtained an NPI?

If a pharmacy or pharmacies have already obtained their NPI(s), it is important that the number(s) are communicated to NCPDP so that the number(s) can be added to the NCPDP Pharmacy Database. Adding NPIs to the Pharmacy Database is a vital method of dissemination of new NPIs by pharmacies and will aid in avoiding possible payment disruptions – already identified by the health care industry as a major potential issue when transitioning from old numbers to the NPI. Many payers intend on continuing to use "legacy" or "proprietary" identifiers in their claims processing systems and therefore intend on "cross walking" the new NPI to the legacy number (e.g. the NCPDP Provider pharmacy ID). The NCPDP Pharmacy Database provides this cross walk to subscribers of the database.

What Must NCPDP Do Next?

NCPDP will take several steps when CMS has completed testing. NCPDP must register as an EFIO with CMS and an authorized official of NCPDP must complete and sign a certification statement and mail it to

the CMS Enumerator, Fox Systems, Inc. NCPDP cannot submit live files until this has been completed.

As stated earlier, NCPDP is collecting all of the relevant data from those pharmacies on whose behalf NCPDP will act. NCPDP will enter it into NCPDP Pharmacy Database. According to CMS, NCPDP must certify that data submitted is not greater than twelve (12) months old. This is why NCPDP is requesting that pharmacies update their data with NCPDP, even if they believe nothing has recently changed.

Once CMS is ready to enumerate, NCPDP will create the XML file required by CMS for submission to NPPES and upload (transmit) the file(s) electronically to NPPES. NCPDP will then receive two emails from NPPES. The first contains the NPPES-generated file name. The second indicates whether the file upload was successful.

Once a file is submitted to NPPES, it is placed in a "queue". This means that the file is held until the Enumerator is ready to have NPPES review it. Once the file is removed from the queue, its contents – including each pharmacy's record – will be run against NPPES and its edits. Typically, no later than six business days after the file is released from the queue, NCPDP will receive an email from NPPES stating that the file has been processed and can be downloaded by NCPDP.

For records that successfully pass all edits and validations, NPIs are assigned for each pharmacy. NPIs will be included in a return file that NCPDP can download. NCPDP will then notify a pharmacy or pharmacy chain of its NPI(s). Some records may require Enumerator intervention, especially if the pharmacy is requesting an additional NPI(s). NPPES will make available to NCPDP a return file that will contain codes that indicate the status of each record pending with the Enumerator. In this scenario, the Enumerator may contact NCPDP for assistance in resolving discrepancies involving certain records.

Pharmacy chain data will likely be submitted to NPPES in distinct batches to simplify the administrative activities surrounding enumeration and resubmission of rejected or pended records for the Enumerator, NCPDP and the chain's contact person.

Where Can I Find More Information?

For more information on the pharmacy NPI, NCPDP's role as an EFIO or the pharmacy industry's timeline on converting to the NPI, visit the NCPDP web site at http://www.ncpdp.org/frame_news_npi-info.htm

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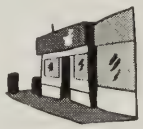

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Continuing Education for Pharmacists

Volume XXIII, No. 1

Natural Products: Calcium to Capsicum

J. Richard Wuest, R.Ph., Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

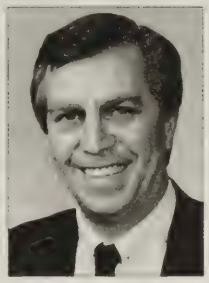
Goals. The goals of this lesson are to present information on the claims, mechanisms of action, typical dosages used and other items of interest on natural products and nutraceuticals alphabetically from calcium to capsicum, and to provide background information for assisting others on their proper selection and use.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. identify claims, mechanisms of action, and typical dosages for natural products and nutraceuticals presented;
2. select from a list, the synonyms for these products; and
3. describe popular uses of the products discussed.

This lesson is part of a series that presents an overview of the common uses, proposed mechanisms of action, typical dosage regimens and other information of interest on natural products and nutraceuticals.

Gossel



Wuest

The paramount difference between drugs and natural products was explained in the first lesson in this series. However, since natural products are a controversial topic for some people, the authors restate that the information presented is neither a promotion of nor a condemnation against their use. It is merely an overview of what has been reported in both the public and scientific literature, and certainly not an in-depth treatise.

Calcium (available as calcium acetate, calcium ascorbate, calcium aspartate, calcium carbonate, calcium chelate, calcium chloride, calcium citrate, calcium gluconate, calcium lactate, calcium lacto-gluconate, calcium phosphate, dicalcium phosphate, hydroxy-apatite, oyster shell calcium and tricalcium phosphate) is the most abundant cation in the body and the fifth most abundant element (after oxygen, nitrogen, sulfur and hydrogen).

The average adult human body contains 21 to 25 grams of calcium per kilogram of fat-free tissue for a total of more than one kilogram of calcium per total body weight. Over 90 percent of calcium is in skeletal tissue and teeth which serve as a reservoir of calcium for its continual function throughout the body. The remaining 10 percent is distributed almost equally between intracellular and extracellular fluids. Normal calcium serum values are 4.5 to 5 mEq/liter (~10mg/dL). Of this total, 50 percent is present as calcium ion, another 5 percent is complexed with phosphate, citrate and other anions, while the remaining 45 percent is protein-bound, awaiting use wherever needed.

Vitamin D and parathyroid hormone are required for proper absorption and excretion of calcium. There is an intricate mechanism within the parathyroid gland whereby the body measures the serum calcium content. When this concentration is too high, it exerts a negative feedback control via calcium-sensing receptors within the gland, which then decreases the amount of calcium absorbed from the dietary intake.

In addition to Vitamin D, phosphate ions and magnesium reduce the fluctuation of calcium from its normal concentration. From person to person, there are wide variations in calcium intake and excretion during a 24-hour period. In spite of this, in healthy individuals, parathyroid hormone, vitamin D, magnesium and inorganic phosphate salts assure that the body has enough, but not too much, ionized calcium available in the blood for its many different functions.

Calcium plays many vital roles in a variety of physiological and biochemical processes within the human body. In addition to being the principle component of skeletal tissue and imparting the structural integrity of bone and teeth, calcium is involved in the function of nearly every type of cell and tissue in the

Table 1
Functions of Calcium in the Body

- blood coagulation
- cell membrane and capillary permeability
- cellular adhesiveness
- contraction of heart, smooth and skeletal muscle
- enzyme activity
- nervous, muscular and skeletal tissue function
- renal function
- respiration
- storage and release of hormones and neurotransmitters
- uptake and binding of amino acids in cells

body. It is essential for proper maintenance and functioning of the cardiovascular, renal, endocrine, central nervous, pulmonary and metabolic systems. Functions of calcium in the body are summarized in Table 1.

The major food source for calcium is milk and other dairy products. Other foods with relatively high calcium content include apricots, bok choi, broccoli, cabbage, mustard greens, salmon, sardines and tofu.

Calcium must be in a soluble form to be absorbed. Gastric acidity increases solubility, as does vitamin C and some amino acids. The lactose in milk forms a soluble complex with calcium, thus enhancing the value of dairy products as a food source. Additionally, milk is fortified with vitamin D which also enhances calcium absorption.

A deficiency of blood calcium levels (hypocalcemia) is rarely due to an insufficient amount being present in dietary intake. Rather, it is generally caused by either inadequate parathyroid hormone production or decreased intestinal absorption of calcium. The latter is due to vitamin D deficiency or a malabsorption disease such as celiac disease, chronic biliary obstruction, chronic pancreatitis, cystic fibrosis, diverticulitis, enteritis or sprue.

The most prominent symptom of hypocalcemia is increased neuromuscular activity. This will eventually lead to tetany, which begins with numbness and tingling in the hands and feet followed by muscle spasms. These are often exhibited as twitching of facial muscles and can continue on to epileptic-like convulsions. With hypocalcemia, there are progressively worsening abnormal EKG readings.

Regardless of the cause, acute hypocalcemia must be treated with intravenous infusion of calcium gluconate, since there is generally a problem with absorption that has resulted in the deficiency. Calcium chloride is rarely used for this, since it can be very irritating to veins when injected.

Other skeletal diseases associated with calcium deficiency are rickets, osteomalacia and osteoporosis. Rickets is a vitamin D deficiency that causes a variety of bone deformities in children. Rickets in adults is called *osteomalacia*. The more common disorder in adults, osteoporosis, leads to easy fracturing of bones.

Injectable Calcium Salts. The FDA-approved indications for calcium-containing injectables follow.

1. FDA has approved calcium-containing injectables for treatment of hypocalcemia due to rapid fetal growth during pregnancy and in those conditions which require a prompt increase in blood plasma calcium levels, such as neonatal tetany and tetany due to parathyroid deficiency, vitamin D deficiency and alkalosis. Other therapy, such as parathyroid hormone or vitamin D may be indicated according to the etiology of the tetany. It is also important to institute oral calcium therapy as soon as possible.

2. They are approved for the treatment of magnesium intoxication or depression due to overdosage of magnesium sulfate.

3. They are also approved to combat the deleterious effects of hyperkalemia as measured by electrocardiogram, pending correction of the increased potassium level in the extracellular fluid.

Calcium injection may also be used in cardiac resuscitation when epinephrine injection has failed to strengthen myocardial contractions.

Calcium injection has reportedly also been used as adjunctive therapy for severe insect bites or stings, to decrease capillary permeability in sensitivity reactions, to treat nonthrombocytopenic purpura and exudative dermatoses (such as dermatitis herpetiformis), and for severe itching around drug-induced eruptions of the skin. Calcium salts (usually calcium gluconate injection) are used as an electrolyte supplement in total parenteral nutrition (TPN) infusions.

There are a few unapproved, but nonetheless medically acceptable (i.e., off-label), uses for injectable calcium including calcitriol-resistant rickets, rhabdomyolysis, cardiopulmonary bypass, hypocalcemia associated with acute pancreatitis, and calcium channel blocker overdose.

Oral calcium supplements are prescribed for glucocorticoid-induced osteoporosis, for leg cramps associated with pregnancy, to lower LDL levels in patients with hypercholesterolemia, to prevent the development of hypertension, to treat osteomalacia and to prevent and treat osteoporosis. Calcium carbonate is an FDA-approved OTC antacid, and calcium carbonate and calcium acetate are used as phosphate binders in patients with renal failure.

Claims are made that oral calcium is useful in reducing the risk of colorectal cancer, treating diarrhea, reducing excess fluoride in children and treating premenstrual syndrome.

Table 2
Daily Dietary Reference Intake of Elemental Calcium

Age	Dietary Intake
1 to 3	500 mg
4 to 8	800 mg
9 to 18	1300 mg
19 to 50	1000 mg
over 50	1200 mg
pregnant or lactating women under 19	1300 mg
pregnant or lactating women 19 and older	1000 mg

From a legal standpoint, oral calcium supplements are natural products for dietary supplementation. They are not "drugs." The labels for calcium-containing nutritional supplements are not controlled by FDA in the same manner as are nonprescription drugs. Manufacturers of oral calcium supplements, therefore, cannot make direct therapeutic claims on the label. If a therapeutic claim is made, by law the product is a drug, and requires an FDA-approved NDA, just like injectable drug products.

Many manufacturers/distributors of calcium supplements avoid problems by making claims in other media rather than on the actual product label. The latter will contain "weasel words" such as "clinically proven to ...;" "helps promote or maintain ...;" "assists the body in ...;" "a natural way to enhance ...;" "to support a healthy ...;" etc. The disclaimer "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease." is printed on the label and any promotional materials.

The typical doses of calcium (measured as elemental calcium) used in clinical studies to prove effectiveness in reducing bone loss range from 500 to 1600 mg, divided into three or four doses daily. The daily Dietary Reference Intake (DRI) amounts of elemental calcium are listed in Table 2.

The two major salts used for calcium supplementation are the carbonate and citrate forms. Calcium carbonate consists of approximately 40 percent elemental calcium, which means a 1 gram dose contains 400 mg of elemental calcium. Calcium citrate consists of approximately 21 percent of elemental calcium. This means a 1 gram dose of calcium citrate contains 210 mg of elemental calcium.

To determine a proper amount of either salt to obtain the DRI of elemental calcium, the following ratios can be used to calculate the dose:

Calcium carbonate: 2500 mg = 1000 mg of elemental calcium.

Calcium citrate: 4700 mg = 1000 mg of elemental calcium.

Calendula (*Calendula officinalis*), also known as garden marigold, gold bloom, holligold, marigold, marybud and pot marigold, is thought to have originated in Egypt many centuries ago. It is now grown in most fertile parts of the planet. Legend has it that the plant was given its name because it has a tendency to bloom in harmony with the lunar calendar, every month during the new moon phase in the southern Mediterranean region.

There are a wide variety of plants in the marigold family. All have a pungent odor and some are used as seasoning in food. A reference point for familiarity of what calendula looks like is the yellow-orange round marigold flowers people plant in their gardens. It is believed that the pungent odor is an effective pesticide which repels insects.

The flowers of calendula are used orally as an antispasmodic, to initiate menses and reduce dysmenorrhea, treat cancer and heal gastric and duodenal ulcers. It is also used as a gargle to treat inflammation of the mouth and pharynx. Topically it is used to promote healing of wounds and leg ulcers.

Claims are made that there is some clinical evidence that calendula has antibacterial, antiviral and antitumor activity *in vitro*, and that it stimulates granulation tissue in wounds. In this country, these claims are not accepted by FDA.

On the adverse side of the story, calendula can cause an allergic reaction in persons sensitive to chrysanthemums, daisies, marigolds, ragweed and many other plants and herbs.

When used orally, a typical dose for calendula is one cup of tea, three times a day. The tea is prepared by steeping 1 to 2 grams of dried flower in 150 mL of boiling water for five to 10 minutes. The resulting solution is strained before drinking. The tincture (1:5 ratio in 90 percent alcohol) is usually taken as a 0.3 to 1.2 mL dose three times a day.

Calendula tea is used as a mouthwash. It is also applied topically after soaking an absorbent cloth in the tea and then applied as a poultice to the inflamed or wounded skin. When the tincture is used topically, typically 2 to 4 mL is diluted with 0.25 to 0.5 liter of water.

Capsicum (*Capsicum annuum*; *C. frutescens*), is also known as African chilies, capsaicin, cayenne pepper, chili pepper, goat's pod, green pepper, hot pepper, Hungarian pepper, Louisiana sport pepper, Mexican pepper, paprika, pimento, red pepper, sweet pepper and tabasco pepper. The plant is a spreading annual shrub indigenous to tropical America that was initially described to Europeans by a physician who accompanied Christopher Columbus on one of his voyages to the West Indies in the late 1400s. The name was derived from the Latin word "capsa", or box, which referred to the partially hollow, box-like shape of its fruit.

There are several species and many hybrids of the group of plants referred to as peppers that are used as spices. There are two other familiar pepper-based species. *Piper nigrum* is the source of black and

white pepper that accompanies salt on the dining table. Bell peppers (green, orange, red and yellow) constitute the species used in salads and to spice up meals. These three types of peppers are the most widely consumed spices in the world.

This section focuses on capsicum, preparations of which have been used for centuries. Native Americans, calling the plant cayenne, ingested it for antispasmodic, aphrodisiac, carminative, digestive aid and purgative (bowel cleansing) properties. They also used it topically as a counterirritant to relieve itching and muscle pain.

Today in folk medicine, people take capsicum orally as an antiflatulent; for colic, cramps, and diarrhea; to reduce blood cholesterol and clotting; to increase peripheral circulation; to treat motion sickness, alcoholism, and fever; and to prevent arteriosclerosis and heart disease.

Capsaicin, a component of capsicum oleoresin, has attained FDA approval as a safe and effective drug for nonprescription use. It has a chemical structure similar to eugenol, which is the active principle of oil of cloves, and has proven local analgesic activity. In the U.S., topical creams, gels and lotions contain capsaicin in strengths of 0.025 and 0.075 percent. They are approved for OTC sale for temporary relief of pain from rheumatoid arthritis and relief of neuralgias such as pain following shingles (herpes zoster) or painful diabetic neuropathies. They are also used for HIV-associated peripheral neuropathies, post-herpetic flareups and for trigeminal neuropathies. Capsin, Pain-X and Zostrix are among the commercially available products.

In homeopathic medicine, capsicum is used for inflammation of the urinary tract, gastrointestinal tract, mouth and throat. It is also used for middle ear infections.

The mechanism of action for capsaicin is proposed to be stimulation of release of substance P (a mediator of pain) in nerve endings to eventual depletion. When adjoining neurons take in this substance, they fire and transmit impulses along the CNS to the brain which perceives the sensation as itching in low levels of stimulation and pain in higher levels.

When first applied, capsaicin produces sensations ranging from warming to burning. However, after repeated application, substance P is depleted in that area. This reduces the ability of the affected neurons to transmit impulses, thus alleviating pain and itching. It may take as long as three days for full therapeutic effects to occur.

Proof of therapeutic effects for capsicum or any of its components when taken orally is lacking at this point in time. However, its irritant effects are the basis for its use in many of the self-defense products (pepper sprays) on the market.

Capsicum can induce adverse reactions when taken orally. It can cause gastric irritation, sweating and flushing of the face and neck, and increased tearing and runny nose. Excessive ingestion of capsicum has reportedly resulted in gastrointestinal, liver and kidney damage.

The most well-known adverse effect of capsicum is undoubtedly the intolerable burning sensation that follows contact with mucous membranes. In fact, this is the reasoning behind its use in self-defense products. When sprayed into the eyes, it causes immediate blindness and irritation that can last up to 30 minutes, without permanent damage.

On the self-medication side of the picture, it is imperative that those who apply capsaicin-containing products wash and dry their hands thoroughly after each application. They must avoid accidental touching of their own eyes, mouth, nasal passages and other mucous membranes and transitional skin (i.e., lips, nipples, external genitals), as well as those of other persons.

If such contact does occur, the area should be thoroughly flushed with lots of water. There are anecdotal, but not scientifically proven, reports that the use of milk to flush the irritated mucous membranes is beneficial.

Allergic reaction to capsicum and its components has been reported in persons sensitive to anise, avocados, bananas, bell peppers, birch pollen, black and green peppercorns, celery, chestnuts, coriander, cumin, fennel and kiwi.

In folk medicine, typical oral doses of capsicum are 30 to 120 mg of dried capsicum fruit, 0.6 to 2 mg of capsicum oleoresin or 0.3 to 1 mL of capsicum tincture. The usual frequency of these doses is three times a day.

For topical use, the approved labeling of capsaicin-containing OTC products (0.025 and 0.075 percent) states that they can be applied to affected areas a maximum of three to four times a day.

Continuing Education Quiz

This month's questions are taken from the article on "Natural Products: Calcium to Capsicum". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 1/15/08. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-05-001-H01.

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City, State, Zip_____

Daytime Phone_____

Date Completed _____
(*Required*)

The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education for pharmacists.

1. Which of the following is the most abundant cation in the body?
   a. Calcium
   b. Iron
   c. Potassium
   d. Sodium

2. Which of the following vitamins is required for proper absorption and excretion of calcium?
   a. Vitamin A
   b. Vitamin B
   c. Vitamin C
   d. Vitamin D

3. Which of the following hormones assures that the body has sufficient ionized calcium available in the blood?
   a. Cortisol
   b. Insulin
   c. Parathyroid
   d. Somatropin

4. The most prominent symptom of hypocalcemia is:
   a. decreased neuromuscular activity.
   b. increased neuromuscular activity.

5. The calcium salt that is usually used as an electrolyte supplement in total parenteral nutrition (TPN) infusions is:
   a. calcium acetate.
   b. calcium citrate.
   c. calcium gluconate.
   d. calcium lactate.

6. The calcium salt that contains the highest percentage of elemental calcium per 1 gram dose is:
   a. calcium carbonate.
   b. calcium citrate.

7. Calendula is a member of which of the following families of plants.
   a. Carnation
   b. Hollyhock
   c. Lily
   d. Marigold

8. The flowers of calendula are used for all of the following EXCEPT:
   a. as an antispasmodic.
   b. to alleviate acne vulgaris.
   c. to reduce dysmenorrhea.
   d. to treat inflammation of the mouth.

9. Capsicum is also known by all of the following names EXCEPT:
   a. bell pepper.
   b. cayenne pepper.
   c. paprika.
   d. pimento.

10. Which of the following has attained FDA approval as a safe and effective drug for nonprescription use?
   a. Calendula
   b. Calcium lactate
   c. Capsaicin

Maryland Pharmacists
Duty to Report

Code of Maryland regulations
10.34.10.05. Duty to Report.

A. Except when the conduct in question includes drug or alcohol abuse or dependency, a pharmacist shall report to the Board:

(1) Conduct which violates a statute or regulation pertaining to the practice of pharmacy;

(2) Conduct by a pharmacist that deceives, defrauds, or harms the public; and

(3) The unauthorized practice of pharmacy.

B. A pharmacist shall report to the pharmacist rehabilitation committee, as defined in Health Occupations Article, § 12-317, Annotated Code of Maryland, conduct by a pharmacist that involves drug or alcohol abuse or dependency.

Practically speaking this means:

1) If you are aware of a fellow pharmacist who is impaired by drugs or alcohol you have a legal obligation to report it,
2) The mechanism for reporting is the Pharmacists' Education and Assistance Committee (PEAC),
3) The Board of Pharmacy can sanction you if they become aware that you could have but did not report such a case.

Simply, you have an easy, anonymous way to protect yourself, your fellow pharmacist and the public by making a referral to PEAC. Failure to report such a case violates Maryland Pharmacy Regulations and could adversely affect your own ability to practice pharmacy.

To make a referral or to learn how PEAC provides confidential help to an impaired pharmacist contact:
Pharmacists' Education and Assistance Committee
Phone (410) 983-0302 or (410) 706-7513
E-mail PEAC@direcway.com
Website www.peacmaryland.org

Pharmacists' Education & Assistance Committee of Maryland

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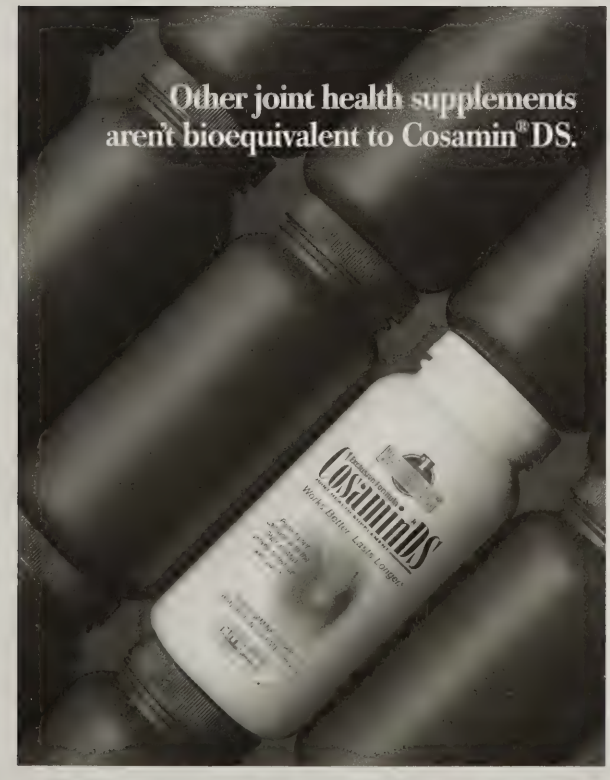

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MARYLAND
Pharmacist
VOLUME 82 NO. 3

President's Address
"Virginia Apyar, P.D."

The Maryland P3 Project
"The Program"

Therapeutically Speaking...
"Lyrica®: Just Another "Me Too" for Neuropathic Pain"

Continuing Education
"A New Era in the Management of Diabetes: Inhaled Insulin"

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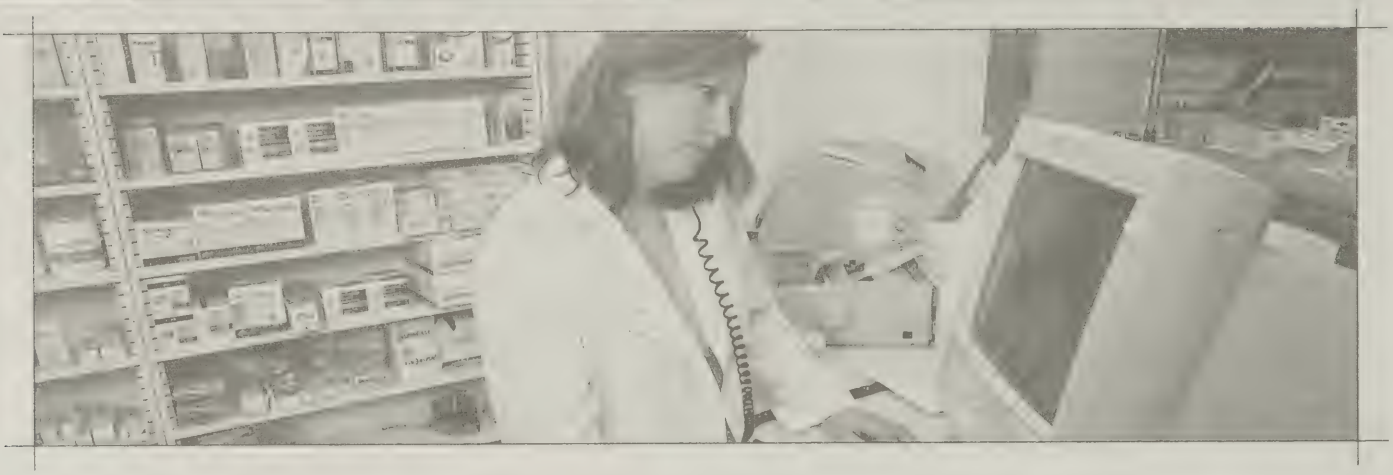

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President's Address

Virginia Apyar, P.D., President

As I assume the duties as your 122nd President of the Maryland Pharmacists Association, I think back on how I became involved in MPhA. I was the pharmacist-in-charge for a chain that had a store on 94th St. at the Ocean Plaza Mall in Ocean City. The Roche salesman came in one day to introduce himself and I asked him about the state association. He was a wealth of information. Soon after that I was invited to an Eastern Shore Pharmaceutical Society meeting and then became a member of MPhA. That was back in 1985.

In preparation for my year as president our Executive Director had me attend the Sanofi-Aventis Pharmaceuticals Pharmacy Leadership Conference in Denver, CO. There I was able to meet president-elects from other states and found out that we share the same challenges and problems. What amazed me was, while the challenges and problems were mutual, MPhA was in a much better situation to over come and work through the problems facing the practice of pharmacy. Pharmacy always seems to be in an environment that is in a constant state of flux. Currently, we can see forward movement with medication therapy management services as a defining goal. Howard and I attended the 36th Annual Southeastern Pharmacy Officers Conference held in Charleston, SC. The topics that were discussed at the conference table were not all limited to reimbursement issues. Quality and medication errors, compounding, conscience clause, importation, DOD mandatory mail, the federal government regulating pharmacy thus eliminating the need for boards, the national cost of dispensing study to mention a few.

Our Past-Presidents and Board of Trustees over the last few years have revamped our Association through By-Laws changes and our Board structure. The changes they have implemented are too many to list, from a new logo to the strength of the Maryland Pharmacy Coalition. All of these endeavors have advanced our association. By doing such a terrific job in the past this year we can fully concentrate on the legislative issues coming to the General Assembly and the P-3 Project. Success of the P-3 Project will define the practice of pharmacy in Maryland.

A colleague phoned me to congratulate me on my new office. He said he used to be a member of MPhA. When I asked him why he let his membership lapse he said he didn't get anything out of being a member. My response was, the return on your investment as a member depends on the energy you put forth. Our Newsletter gets rave reviews on keeping the membership informed. To some, that is the value for them in membership. To truly experience the value of an association at some point in time participation at our two yearly meetings, being involved on a committee or attending the Board of Trustees meeting makes one a major stakeholder in the momentum of the Association. In my first candidate statement when I ran for a Trustee seat, I closed saying if elected I hoped to exceed the member's expectations of the Association. I still feel the same, and with our Chairman of the Board Matthew Shimoda and Vice-President Joseph Marrocco, I know MPhA will continue to grow and exceed the member's expectations. It is an honor and privilege to serve as your President.

Yours truly,

Ginger

The Maryland P3 Program

Program Description

The Maryland P3 Program (Patients, Pharmacists, Partnerships) is designed to apply a proven healthcare model that improves the quality of care and reduces overall health care costs. The first target group consists of patients with diabetes in Allegany County, Maryland. With success, the program will expand throughout Maryland.

The Maryland P3 Program replicates the highly successful Asheville Project. This program provides participating employers with the support and tools to link employees, retirees, and their dependents, as well as Maryland Medical Assistance patients enrolled in Maryland Physicians Care with community pharmacists to help them manage their diabetes. Regular patient visits and active communication with the participant's physician and other health care providers assures good outcomes. A distinctive program component is a diabetes credential that the patient can earn through program participation that acknowledges the participant is capable of self-managing their condition.[2]

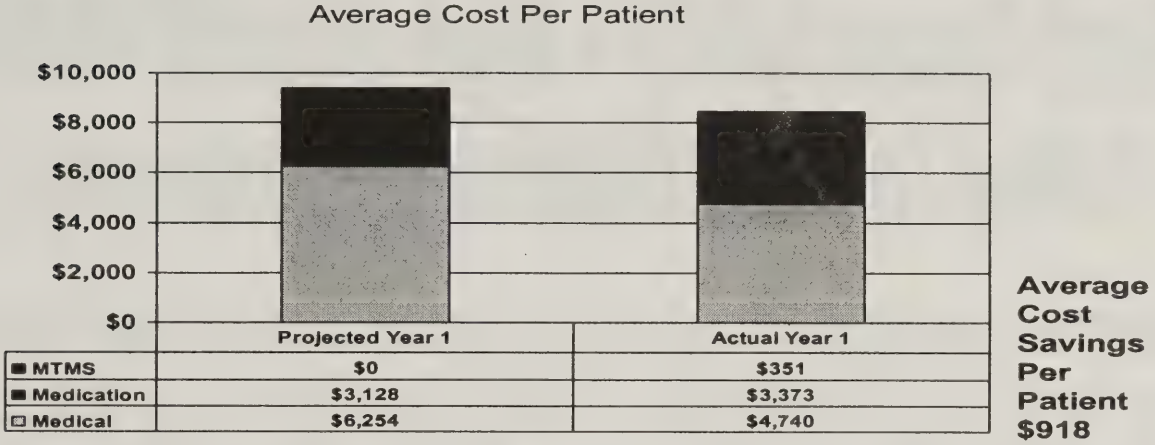
Success of the Model

The model that will be utilized in this program aligns incentives that encourage collaboration among health care stakeholders to provide patients with a service that will teach them how to better self-manage their diabetes and improve their overall health, which in return reduces overall medical costs. Aligned economic incentives begin with the employer or public payer who provides an incentive to patients, such as waived co-payments for diabetes-related medications or gift certificates. The program also provides payment to the pharmacists for providing education and diabetes care management. The employer or public payer will receive a return on investment as a result of healthier workers, decreased absenteeism and a decrease in overall health care costs.

APhA Foundation's Patient Self-Management Program has resulted in[2]:

- A savings of approximately $918 per employee in total health care costs for the initial year, with an even greater savings in subsequent years
- Return on investment (ROI) of at least 4:1 beginning in the second year
- A 50% reduction in absenteeism and fewer worker compensation claims
- High employee satisfaction – 95% approval for pharmacist care – and improved quality of life
- Employees savings an of average $400-$600 per year through incentives

Patient Self-Management Program℠ for Diabetes: First Year Cost Savings



Align the Incentives, Empower the Patient, Control the Costs℠

Collaborating Partners

The Maryland Pharmacists Association will serve as the coordinator of the network of participating pharmacists. The University Maryland School of Pharmacy will provide educational program development, pharmacist training, and analysis of outcome data. The Department of Health and Mental Hygiene will also receive data for program evaluation. Maryland Physicians Care and self-insured employers in Allegany County will make the program available on a voluntary basis to their beneficiaries with diabetes. Technical advice and implementation materials will be provided by the American Pharmacist Association Foundation, which is a non-profit organization whose mission is to improve the quality of patient health outcomes that can be affected by pharmacy. This program is a result of a collaboration of the Maryland General Assembly, Department of Health and Mental Hygiene, University of Maryland, School of Pharmacy, Maryland Pharmacists Association, and Maryland Pharmacists.

If you would like more information about the Maryland P3 Program please contact Dr. Christine Lee by email at clee@rx.umaryland.edu.

[1]Cranor CW, Bunting BA, Christensen DB. The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program. *J Am Pharm Assoc.* 2003; 43:173-84

[2]Garrett DG, Bluml BM. Patient Self-Management Program for Diabetes: First-Year Clinical, Humanistic, and Economic Outcomes. *J Am Pharm Assoc.* 2005; 45:130-137

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Rx AND THE LAW

By Kerianne M. Hanson & Don R. McGuire, Jr., R.Ph., J.D.

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COMBAT METHAMPHETAMINE EPIDEMIC ACT:
WHAT THIS ACT MEANS FOR YOUR RETAIL SETTING

On March 9th, 2006, President Bush signed the Patriot Act, which includes a portion known as the Combat Methamphetamine Epidemic Act of 2005.[1] In light of this law, the sale of pseudoephedrine-containing products across the nation is set up for big changes, and the responsibility of enforcing these changes has landed on the shoulders of licensed pharmacists in retail settings.

Pseudoephedrine is a decongestant found in multiple products used to treat symptoms associated with the common cold and seasonal allergies.[2] It is also the primary ingredient needed to manufacture methamphetamine, an illicit drug that has rapidly gained popularity in the U.S. over the past few years. The new regulations regarding the sale of pseudoephedrine are intended to curb the manufacturing of methamphetamine by making it more difficult to accumulate large amounts of pseudoephedrine and by keeping a record of all pseudoephedrine purchases.

The Combat Methamphetamine Epidemic Act categorizes pseudoephedrine as a controlled substances and regulates, among other factors, the amount of pseudoephedrine sold to individuals. Although some states, particularly in the Midwest, have been regulating the sale of pseudoephedrine for over a year now, the Combat Methamphetamine Epidemic Act makes the regulations federal law. Beginning September 30, 2006, patients everywhere in the nation will need to visit a pharmacy in order to purchase pseudoephedrine-containing products.

It is important to keep in mind that some of the specific regulations, such as who in the pharmacy is allowed to sell the products (i.e. pharmacists only, technicians, interns, etc.) and the number of boxes which can be sold in a single transaction, have been left up to the individual states. Pharmacists should check with their State Board of Pharmacy to ensure they are aware of state-specific regulations and train their pharmacy staff accordingly.

Some of the federal regulations regarding the sale of pseudoephedrine-containing products according to the Combat Methamphetamine Epidemic Act are summarized below:[3]

[1] *Legal Requirements for the Sale and Purchase of Drug Products Containing Pseudoephedrine, Ephedrine, and Phenylpropanolamine.* U.S. Food and Drug Administration. Accessed May 24, 2006. **www.fda.gov/cder/news/methamphetamine.htm**.

[2] *Lexi-Comp's Drug Information Handbook.* 13th ed. Hudson, OH: APhA; 2005:1275-76.

- All pseudoephedrine-containing products must be kept behind the counter.
- An individual may purchase no more than 3.6 grams of pseudoephedrine in one day.
- An individual may purchase no more than 7.5 grams of pseudoephedrine in any 30-day period.
- The purchaser must present a State or Federal Government issued photo identification card at the time of purchase.
- Either a written or electronic logbook of all pseudoephedrine transactions must be kept by the pharmacy for a period not less than two years from the date of purchase.
- For each sale, information including the name and address of the purchaser, the name of the product, the quantity purchased, and the date and time of the transaction must be collected and entered into the logbook. Many states will also require additional information be collected, such as the purchaser's birthday or a driver's license number.
- Products packaged for individual sale that contain less than 60 milligrams of pseudoephedrine are exempt from the logbook requirements but must also be kept behind the counter.
- The pharmacist must confirm the information provided by the purchaser matches that provided on the identification card.
- The purchaser must provide a signature verifying the information provided is correct.

In response to the new regulations, and in an effort to further hinder methamphetamine production, many product manufacturers have voluntarily re-formulated their products to contain alternative decongestants such as Phenylephrine. These products, commonly identified by the letters PE (ex. Sudafed® PE), may offer alternatives to patients who need decongestant products on a daily basis. It is also important to recognize that the majority of the regulations established by the Combat Methamphetamine Epidemic Act do not apply to prescription products containing pseudoephedrine, but these products will be classified as controlled substances, and regulations set forth by the Controlled Substance Act 1970 are now applicable.

Complete information regarding the Combat Methamphetamine Epidemic Act and the regulations it sets forth are available on the Food and Drug Administration's website (www.fda.gov) and from each individual state's Board of Pharmacy.

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Kerrianne M. Hanson is a Pharm.D/MBA Candidate at the Drake University College of Pharmacy in Des Moines, Iowa. Don R. McGuire Jr., R.Ph., J.D. is Assistant General Counsel, at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

[3] The Library of Congress. *Title VII: Combat Methamphetamine Epidemic Act of 2005.* House Report 109-333. Accessed May 24, 2006. http://thomas.loc.gov/cgi-bin/cpquery/?&dbname=cp109&sid=cp109djs6R&refer=&r_n=hr333.109&item=&sel=TOC_358801&>

Lyrica®: Just Another "Me Too" for Neuropathic Pain?

Laura Scarpaci, Pharm.D.
Palliative Care Resident, University of Maryland School of Pharmacy
Edited by Mary Lynn McPherson, Pharm.D., BCPS, Professor, University of Maryland School of Pharmacy

Approved in 2005 by the FDA, Lyrica® (pregabalin) is one of several agents recently added to our analgesic armamentarium. In addition to being approved as adjunctive therapy for patients with partial onset seizures, it is also indicated to treat painful diabetic peripheral neuropathy and postherpetic neuralgia.[1] Pregabalin has been described as being just another "me too" drug or "son of gabapentin." It is true that pregabalin and gabapentin share a number of similarities including chemical structure, mechanism of action, and therapeutic utility, but are there any distinctions that warrant recommending pregabalin over gabapentin?

Neuropathic pain may be experienced by patients with a variety of disease states, including diabetes mellitus, herpes zoster or shingles, HIV, and cancer among others. Of the 14 million people diagnosed with diabetes in the United States, between 20-24% suffer from peripheral neuropathy.[2] Furthermore, between 15-48% of patients with a herpes zoster outbreak develop neuropathic pain with higher prevalence in older adults.[3] Patients with neuropathic pain incur on average three times greater annual health care costs than those without neuropathic pain. Additionally, painful neuropathy has been associated with decreased quality of life due to fatigue, depression, interference with interpersonal relationships and activities of daily living.[2]

Neuropathic pain is a consequence of nerve damage; patients typically describe such pain as electric, tingling, shooting, or burning in quality. Patients suffering from neuropathic pain may also complain of a pain in response to a normally non-noxious stimulus such as the touch from a bed sheet (allodynia) or an exaggerated painful response to a normally noxious stimulus, such as a hot shower feeling like scalding water (hyperalgesia). Medications such as the tricyclic antidepressants, anticonvulsants, opioids, capsaicin, and lidocaine have been traditionally employed to manage neuropathic pain. Recently two new medications have been approved for the management of neuropathic pain: Cymbalta® (duloxetine), the first non-tricyclic antidepressant with an indication for neuropathic pain, and Lyrica® (pregabalin).

Pregabalin is classified as a gamma-aminobutyric acid (GABA) analog, similar to gabapentin (Neurontin®). Although its exact mechanism of action is still unknown, pregabalin, like gabapentin, appears to bind selectively with high affinity to the alpha$_2$-delta subunit of voltage-gated calcium channels in central nervous system tissues.[4] *In vitro* studies suggest binding at this site reduces calcium influx into hyperexcited neuron terminals, which subsequently lowers the release of several neurotransmitters (i.e. glutamate, norepinephrine, and substance P). It does not seem to have direct GABA-mimetic effects nor bind directly to GABA or benzodiazepine receptors.

In a study by Sabatowski et al. examining post herpetic neuralgia (PHN), 238 patients were randomized in a multi-center, double-blind, placebo controlled trial and received either 150 mg/day (n = 81) or 300 mg / day (n = 76) of pregabalin, or placebo (n = 81).[5] Exclusion criteria included failure to respond to previous treatment for PHN with gabapentin ≥ 1200 mg/day. Significant improvement in mean pain scores was noted in the 150 mg and 300 mg/day pregabalin groups in comparison to placebo (-1.20, p<0.0002; -1.57, p<0.0001, respectively). Improvement in comparison to placebo occurred as early as 1 week and remained significant throughout the study for both treatment groups. There were more responders among the intent to treat population in the 150 (26%, p=0.006) and 300 mg/day (28%, p=0.003) pregabalin groups than in the placebo group (10%). Pregabalin also significantly improved mean sleep-interference score among the intent to treat population.

A study by Rosenstock et al. enrolled 146 patients in a multi-center, double-blind, placebo-controlled, parallel group, 8 week trial examining the efficacy of pregabalin in the treatment of painful diabetic peripheral neuropathy.[6] Patients were randomized to receive pregabalin 300mg/day (n=76) or placebo (n=70). Exclusion criteria included failure to respond to treatment with gabapentin ≥ 1200 mg/day. The mean pain score decreased significantly for pregabalin 300 mg/day (baseline, 6.5; endpoint 4.0) in comparison to placebo (baseline 6.1; endpoint, 5.3; P=0.0001), beginning during the first week and continuing through week 8. Pregabalin also demonstrated a statistically significant improvement in the mean sleep interference score in comparison to placebo.

So what allows pregabalin to stand apart from gabapentin? There are some fine pharmacological differences between the two agents. The oral bioavailability of pregabalin and time to onset of decreased pain is better in comparison to gabapentin (table 1). Unfortunately, at this time, there are no direct head-to-head trials comparing pregabalin to gabapentin in the treatment of neuropathic pain conditions.

There are no significant drug interactions associated with pregabalin use, however, concurrent administration of opioids, benzodiazepines, or ethanol may increase the risk of somnolence and dizziness.[1] Pregabalin is not protein bound, undergoes negligible metabolism, and is eliminated primarily unchanged by renal excretion, with an elimination half-life of 6.3 hours. Pregabalin clearance is decreased in patients with renal impairment and hemodialysis removes pregabalin from the serum, necessitating dosage adjustments. The pharmacokinetics of pregabalin has not been adequately studied in pediatric patients.

Pregabalin is contraindicated in patients with known hypersensitivity to pregabalin or any of its components.[1] If it is to be discontinued, pregabalin should be withdrawn gradually over a minimum of 1 week to minimize the potential of increased seizure frequency in patients with seizure disorders. The most common adverse effects associated with pregabalin include dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, and "thinking abnormal."

Dosing for neuropathic pain associated with diabetic peripheral neuropathy and post-herpetic neuralgia is as follows: initial dose 50 mg three times a day (150 mg/day) in patients with creatinine clearance ≥ 60 mL/min. Dose may be increased to 100 mg three times a day (300 mg/day) within 1 week based on efficacy and tolerability. No evidence supports increased efficacy above dosages of 300 mg/day in patients with peripheral diabetic neuropathy, however patients with post-herpetic neuralgia may be increased to 600 mg/day if they are tolerating pregabalin and remain symptomatic after 2-4 weeks of treatment. Table 2 describes the necessary dosage adjustment for patients with renal impairment or who are receiving hemodialysis.[1]

In conclusion, is pregabalin just another "me too" drug? Pregabalin has several advantages in comparison to gabapentin, including linear pharmacokinetics, improved oral bioavailability, and time to effective dose, however there is a paucity of head-to-head data comparing pregabalin to other agents. Pregabalin is clearly efficacious in the management of neuropathic pain associated with postherpetic neuralgia and diabetic peripheral neuropathy, however, it remains to be seen whether this medication is superior to gabapentin or other agents, such as tricyclic antidepressants or other anticonvulsants.

Table 1 – Comparison of Pregabalin and Gabapentin

	Pregabalin	Gabapentin
FDA-approved pain Indications	Neuropathic pain associated with diabetic peripheral neuropathy (DPN) and post-herpetic neuralgia (PHN)	Neuropathic pain associated with post herpetic neuralgia
Pharmacokinetic profile	Linear Plasma concentration is proportional to dose	Nonlinear Plasma concentration increases disproportionately to the dose
Oral bioavailability	≥90% of dose (No food effect and dose proportional)	60% 900 mg/day 47% 1200 mg/day 34% 2400 mg/day 33% 3600 mg/day
Time to effective dose (PHN)	1 day Effective starting dose of 150 mg/d	9 or more days Titrate to effective dose of 1800 mg/d

Table 2 – Pregabalin Dosing in Patients with Renal Impairment

Creatinine Clearance (CLcr) (mL/min)	Total Pregabalin Daily Dose (mg/day)[a]			Dose Regimen
≥ 60	150	300	600	BID or TID
30 – 60	75	150	300	BID or TID
15-30	25-50	75	150	QD or BID
<15	25	25-50	75	QD
Supplementary dosage following hemodialysis (mg)[b]				
Patients on the 25 mg QD regimen: take one supplemental dose of 25 mg or 50 mg Patients on the 25-50 mg QD regimen: take one supplemental dose of 50 mg or 75 mg Patients on the 75 mg QD regimen: take one supplemental dose of 100 mg or 150 mg				

TID = three divided doses; BID = two divided doses; QD = single daily dose

[a] Total daily dose (mg/day) should be divided as indicated by dose regimen to provide mg/dose.

[b] Supplementary dose is a single additional dose.

[1] Lyrica® (pregabalin) Capsules CV [package insert]. New York, NY: Pfizer, Inc; 2005.

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the maryland poison center's monthly update. news. advances. information.

July/August 2006

Camphor

Approximately 10,000 exposures to camphor-containing products are reported to poison centers in the United States each year. Approximately 80% of cases involve children less than 6 years old. Most poisonings are unintentional or due to misuse of a product. Camphor-containing products include cold sore ointments and liquids, muscle liniments, rubefacients and camphor spirits. Some common brand names include Campho-phenique (10.8% camphor), Mentholatum Ointment (9% camphor), Vicks VapoSteam (6.2% camphor), and Vicks VapoRub (4.7% camphor). Prior to 1983, most fatalities due to camphor ingestions were associated with camphorated oil (20% camphor) being mistaken for castor oil. An FDA ruling in 1983 limits the concentration of camphor in non-prescription products to not greater than 11%. Fatalities are now rare, but serious poisonings still occur. Non-FDA approved ethnic remedies can be found in the U.S. that contain greater than 11% camphor. Recently, patches containing camphor intended for topical use on children were voluntarily withdrawn. Triaminic Vapor Patch (4.7% camphor) and WellPatch Cough & Cold Soothing Vapor Pads (5% camphor) were removed from the market in June and July 2006 due to the possibility of small children removing them and ingesting them.

One gram of camphor in small children has been fatal. This amounts to as little as 2 teaspoonfuls of an OTC product containing 10% camphor! Ingested amounts of less than 30mg/kg are unlikely to produce severe toxicity. Exposure to camphor is often detected because of it's characteristic odor. Camphor-containing liquids are absorbed rapidly from the gastrointestinal tract. Dermal and mucous membrane absorption also occurs; however, serious toxicity with topical exposure is rare. Camphor's mechanism of toxicity is unknown, but it possesses both excitatory and depressant activity. Agitation, delirium and seizures may occur within 520 minutes. Severe symptoms may be preceded by oral irritation, nausea and vomiting, but often occur without warning. Lethargy and coma may follow. Death is secondary to respiratory failure or seizures.

Most ingestions in children warrant immediate referral to an emergency department for an observation period of at least 2-4 hours. There is no evidence that activated charcoal is beneficial. Camphor-induced seizures are treated with benzodiazepines.

DID YOU KNOW THAT... mothballs used to contain camphor?

Years ago, mothballs were made of camphor. Most, if not all, of the mothballs sold in the United States today contain paradichlorobenzene or naphthalene instead. A characteristic odor similar to camphor is evident with these products. The toxicities associated with the ingestion of naphthalene and paradichlorobenzene are very different from that of camphor. Call the Maryland Poison Center at **800-222-1222** for help in diagnosing and treating all mothball and camphor-containing product ingestions.

Post and share this edition of **toxtidbits** with your colleagues. Send any comments or questions to: **toxtidbits**, 410.706.7184 (fax) or Lbooze@rx.umaryland.edu.

Maryland Poison Center
University of Maryland School of Pharmacy

Continuing Education for Pharmacists

Volume XXIV, No. 4

A New Era in the Management of Diabetes: Inhaled Insulin

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goals. The goal of this lesson is to discuss the use of inhaled insulin in management of type 1 and type 2 diabetes mellitus.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. describe key points relative to diabetes, and patient reactions to the use of injectable versus inhaled insulin;
2. identify physical and chemical characteristics that define the overall action of inhaled insulin;
3. explain the physiologic and pharmacologic principles that define the therapeutic usefulness of inhaled insulin; and
4. select, from a list, important points to pass along to patients relative to correct use of inhaled insulin.

This continuing education activity is supported by an educational grant from GlaxoSmithKline.

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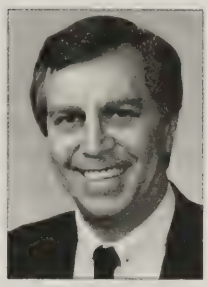

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FDA has approved the first-ever inhaled insulin (Exubera), which is a new alternative to injectable insulin for the more than five million Americans who use insulin. Exubera is the first new insulin delivery option introduced since insulin was first used more than 80 years ago. It is a powder form of recombinant (rDNA) human insulin for the treatment of adult patients with type 1 and type 2 diabetes mellitus (Table 1).

Table 1
Diabetes Facts

- 20.8 million people in the U.S. (7 percent of the population) have diabetes.
- An estimated 14.6 million people (of the 20.8 million) have been diagnosed with diabetes; unfortunately, 6.2 million (nearly one-third of the total) are unaware they have the disease.
- There are 41 million Americans with pre-diabetes, in addition to the 20.8 million.
- To differentiate between pre-diabetes and diabetes, a Fasting Plasma Glucose Test (FPG) or an Oral Glucose Tolerance Test (OGTT) can be done. The American Diabetes Association recommends the FPG because it is easier, faster, and less expensive to perform.
- With an FPG test, a fasting blood glucose value between 100 and 125 mg/dL signals pre-diabetes. A level of 126 mg/dL or higher defines diabetes.
- For the OGTT test, if the 2-hour blood glucose level is between 140-199 mg/dL, the person is pre-diabetic. A value of 200 mg/dL or higher means the person tested has diabetes.
- Persons with pre-diabetes do not automatically progress to diabetes. Those who lose weight and increase their physical exercise can often prevent or delay the disease.
- Among adults with diagnosed diabetes, 16 percent take insulin only, 12 percent take both insulin and oral hypoglycemics, 57 percent take oral hypoglycemics only, and 15 percent take neither insulin nor oral hypoglycemics.

Background on Insulin

The therapeutic insulin era began January 11, 1922, with the first clinical use of insulin following its discovery by Banting and Best. In the ensuing 80 years, scientists discovered the basic pathophysiology of diabetes, elucidated insulin's structure, and directed their attention to developing improved insulin formulations (e.g., NPH, Lente). These advancements led to development and availability of rapid-acting (e.g., aspart, glulisine, lispro) and basal insulin (e.g., glargine) analogs, which have resulted in routine use of insulin regimens that closely approach physiological conditions.

Because insulin is essential in controlling type 1 diabetes, a

noninvasive delivery system is a more convenient alternative. The progressive decline in beta-cell function that is the hallmark in pathogenesis of type 2 diabetes means that many patients will eventually fail on oral antidiabetic therapy and require insulin at some point.

Numerous long-term prospective clinical trials have demonstrated the benefits of tight glycemic control in reducing the risk of secondary complications in persons with type 1 and type 2 diabetes. Other studies have shown that despite the benefits of tight glycemic control, which ultimately may only be achieved with insulin in type 2 diabetic patients, there is reluctance on the part of many patients, and oftentimes their physicians, to initiate insulin therapy. This reluctance may be due to the social stigma of diabetes, lifestyle restriction, sense of guilt or failure, weight gain, perception of worsening pathology, physical limitations to drawing up insulin, or needle anxiety. Physicians, therefore, often prescribe a simple regimen initially in order to assure maximum patient compliance.

It should be stressed that many individuals with type 2 diabetes have a positive regard for injectable insulin in terms of efficacy, prevention of complications, and improved overall health. For various reasons, insulin use may be reserved as a last resort for therapy after the stepwise approach of diet, exercise, and oral antidiabetic agents have failed to produce and maintain adequate glycemic control. However, *many* (some reports say *most*) patients eventually require exogenous insulin to attain glycemic control targets.

Diabetes: The Disease

Despite therapeutic advances, the incidence of both type 1 and type 2 diabetes continues to increase in the U.S. with type 2 at epidemic proportions. Type 1 disease typically develops when the body's immune system destroys the pancreatic beta cells. Risk factors may be autoimmune, genetic, or environmental. There is presently no way to prevent type 1 diabetes.

Type 2 diabetes is associated with decreased sensitivity to insulin in muscle, liver, and adipose (i.e., fat) cells, as well as progressive decline in pancreatic insulin production. The precise causes of insulin resistance with eventual beta-cell failure remain unclear; however, it appears that both genetic predisposition and environmental factors interact. Obesity and sedentary lifestyle are closely linked to both onset and progression of type 2 diabetes; weight loss, exercise, and selective medications can often delay or prevent its onset.

The leading cause of morbidity and mortality in patients with diabetes is cardiovascular disease. A marker of insulin resistance, hyperinsulinemia, is an independent risk factor for cardiovascular disease. Diabetes treatments that decrease hyperinsulinemia and/or insulin resistance seem to protect against cardiovascular events more than treatments that do not impact these factors. Moreover, aggressive treatment of dyslipidemia is critical to effectively manage the complications of diabetes.

However, despite the more favorable time-action profiles of modern insulin analogs, which can help optimize glycemic control, many patients remain suboptimally controlled. Even in teaching institutions throughout the U.S., American Diabetes Association treatment goals are only infrequently attained. For these reasons, the development of a novel, noninvasive, dry-powder insulin delivery system for inhalation use shows promise for adults with type 1 and type 2 diabetes.

Exubera

Exubera is an inhaled dry powder formulation of recombinant (rDNA) human insulin with a particle diameter of 1-5 μm. The powder is contained in blister packs and used in combination with an inhaler device. There are two dosage strengths: each blister contains 1 mg or 3 mg of insulin brought up to a total weight of 5 mg with mannitol, glycine, sodium citrate, and sodium hydroxide. The inhalation system is designed to deliver a fine dry-powder formulation of regular human insulin deeply into the lung in a reproducible and efficient manner.

A blister pack is inserted into the inhalation device (similar to a nebulizer). A pneumatic mechanism is activated by a lever, which punctures the blister. The powder is dispersed in a discrete cloud into the air chamber. The insulin cloud is inhaled slowly, at the beginning of a deep breath. With a bioavailability of 10 to 15 percent and dose equivalence about three times greater than that of injected insulin, each administration delivers the equivalent of approximately 3 IU or 9 IU of subcutaneous (SC) insulin, respectively.

Early studies have shown promising results. Onset of action of inhaled insulin is faster than that of regular human insulin, more closely resembling onset of rapid-acting insulin analogs. Exogenously administered insulin by SC injection has several disadvantages when used in controlling prandial (mealtime) glycemia. Physiologic insulin secretion peaks 30 to 45 minutes after meals and then decreases to basal levels over the next two to three hours. Subcutaneous injection of regular human insulin causes plasma insulin to increase slowly with a peak level achieved 90 to 120 minutes following the injection, and then a slow decline to baseline approximately eight hours after injection. This leads to postprandial hyperglycemia followed by hyperinsulinemia and increased risk of hypoglycemia before the next meal. Although the rapid-acting insulin analogs have reduced some of these difficulties, another problem associated with SC insulin injections is the frequent inter- and intra-individual absorption variation. This appears more often in the

older, type 2 diabetes population, in whom absorption of rapid-acting insulin from SC sites has been shown to be slower than in patients with type 1 diabetes. Inhaled insulin is a viable alternative to prandial injectable insulin administration in patients with diabetes because of its more favorable pharmacokinetic profile and less invasive route of administration. In type 1 diabetes, inhaled insulin is used in combination with a longer-acting injectable insulin. In type 2 diabetes, inhaled insulin can be used as monotherapy, or in combination with longer-acting insulins or oral hypoglycemics.

Clinical Trials. Two 12-week clinical trials evaluated the effect of inhaled insulin in patients with type 1 or type 2 diabetes. These studies demonstrated that patient satisfaction is increased with inhaled insulin compared with injectable insulin. The data showed that improved patient satisfaction is consistently correlated with improvements in glycemic control.

The two 12-week trials were then extended to one year. Patient satisfaction and preference, along with effects on HbA1C levels with inhaled insulin, were compared with an SC insulin regimen both in patients with type 1 or type 2 diabetes. In the 12-week parent studies, patients were randomized to inhaled insulin or SC insulin regimen. In the one-year extension studies, patients were permitted to select their treatment regimen of choice. Patient satisfaction was recorded at baseline (beginning of parent studies), week 12 (end of parent studies), and one-year (extension studies).

Of the 60 patients who received inhaled insulin during the 12-week trials, 85 percent (n = 51) chose to continue treatment, 3.3 percent (n = 8) switched to SC insulin, and 1.7 percent (n = 1) did not continue in the trial. Of the 61 patients who received SC insulin in the 12-week studies, 21.3 percent (n = 13) chose to continue treatment, 75.4 percent (n = 46) switched to inhaled insulin, and 3.3 percent (n = 2) did not continue. From baseline to one year, reductions in HbA1C of 0.8 percent were maintained, and greater improvements were noted in the subjects using inhaled insulin versus those in the SC insulin group, with overall satisfaction of 37.9 percent versus 3.1 percent, respectively.

The Lung as a Site for Insulin Delivery. The lung is an excellent site for drug delivery. The alveolar-capillary network, with a surface area of 140 m^2, is the body's largest microvascular organ and receives the entire cardiac output. Because the lung provides a large surface area for drug absorption, inhaled insulin rapidly attains peak plasma level and metabolic effect. The primary mechanism of insulin absorption across the alveolar capillary and epithelial cells remains unknown, but is believed to be transcytosis (i.e., "across the cells") and formation of insulin vesicles. In this process, insulin molecules are taken up in vesicles by the alveolar epithelial cells. These insulin-containing vesicles are released between epithelial cells and the alveolar capillary endothelial cells. Insulin molecules are then taken up within vesicles by endothelial cells, transported across them, and released into the alveolar capillary blood.

Pulmonary Delivery of Insulin. Following inhalation, pulmonary delivery of insulin results in peak insulin levels within 15 to 20 minutes, with return to baseline 40 to 60 minutes later. If inhaled insulin is not administered correctly, a large portion of the dose will deposit in the upper airways and subsequently be removed from the lung via mucociliary clearance. In order to be absorbed systemically, insulin must be deposited deep within the lung. Two major factors affect its optimal deep-lung deposition: particle size and particle velocity. The optimal particle size for delivery to the alveoli is 1 to 3 μm in aerodynamic diameter. Larger particles will likely be deposited in the oropharynx and upper airways, whereas smaller particles will be lost on exhalation. Independent of particle size, particle velocity also has a major effect on absorption. Inhaled insulin particles must have a low velocity for optimal deposition and absorption.

Safety. The safety of injected insulin is well documented. There is less data to support the safety of inhaled insulin, although in general, studies have confirmed that its safety is comparable with SC insulin. The incidence of hypoglycemia is similar. In animal studies with rats and monkeys, daily inhalation was well tolerated with no evidence of airway or pulmonary lesions.

The American Conference of Governmental Industrial Hygienists has determined that the threshold limit value for inhalation of insoluble "nuisance dust" into the lung is 30 mg/day. Inhaled insulin is rapidly absorbed from the epithelial surface of the lung and therefore will only deposit up to an average of 10 mg of insulin into the lung each day. This means that therapeutic daily doses of inhaled insulin would not be expected to adversely affect pulmonary function. In general, pulmonary function has been stable in patients with type 1 and type 2 diabetes who have been treated with inhaled insulin, and no clinically significant differences in common measures of pulmonary function (spirometry, lung volume, diffusion, capacity or oxygen saturation) have been noted.

An increase in the incidence of mild-to-moderate cough has been reported, which should be expected with inhalation devices. Cough tended to occur within seconds to minutes after insulin inhalation, and lessened with continued use.

Increased antibody formation has been reported with insulin analogs in general. The clinical impact, if any, of such increases has yet to be determined. Pooled data from Phase II and III (three- and six-month) studies of inhaled insulin in patients with type 1 and type 2 diabetes have demonstrated that

Table 2
Patient Advice for Exubera

- Read the *Medication Guide* provided by the manufacturer before you start using Exubera, and each time you get your prescription filled.
- This medicine should not be used if you smoke or have stopped smoking within the past six months. If you decide to start smoking, contact your doctor for a different treatment for your diabetes.
- Tell your doctor if you have unstable or poorly controlled lung disease, or are using any other inhaled medicine.
- This medicine is to be placed in the Exubera inhaler device and inhaled through your mouth into your lungs as directed. The manufacturer states that mealtime doses should be taken 10 minutes before a meal.
- Do not open the blister. The inhaler device will open it automatically. Do not swallow the powder or breathe into the inhaler.
- Follow your doctor's advice on diet, exercise, sleep, personal hygiene, and how to monitor your blood sugar.
- Tell your doctor about all other prescription and OTC medicines, vitamin/mineral supplements, natural products and herbal remedies you are taking. Some OTC medicines (decongestants, aspirin) have a warning on their label advising persons with diabetes not to take them unless directed by a doctor. If you see such a warning on the label of an OTC product, ask your doctor or pharmacist if it is okay for you to take the OTC product.
- Unopened blisters should be stored at room temperature, protected from moisture. Do not refrigerate, freeze or use them after the expiration date on the label.
- After opening the foil overwrap, follow the storage instructions in the *Medication Guide* and use this medicine within three months.
- The inhaler device can be used for up to one year from first use. The release unit should be changed every two weeks.

switching from SC insulin to inhaled insulin is associated with increased antibody levels. However, these increased antibody levels have not caused a need for increased insulin doses or allergic reactions.

Factors that Affect Inhaled Insulin Activity

Smoking. Smoking is reported to be as common in persons with diabetes as in the general population, and is known to increase the permeability of the alveolar-capillary barrier in humans. Smoking may therefore increase absorption of inhaled insulin such that its dose requirements may be lower in smokers. In comparison, SC insulin absorption is decreased in smokers, necessitating larger SC doses. Exubera is contraindicated in patients who smoke or who have discontinued smoking less than six months prior to starting therapy.

Lung Disease. In persons with underlying lung disease such as asthma, COPD, or upper respiratory infections (URI), delivery of inhaled insulin to the blood may be affected by the overall efficiency of pulmonary function. For example, a study showed that subjects with chronic asthma absorb less insulin after inhalation than healthy subjects, resulting in less action to reduce blood glucose levels. The decreased insulin absorption is believed to be caused by a difference in the airway caliber or pulmonary vasculature as a result of chronic lung disease. The patient's physician may suggest that inhaled insulin not be used during intermittent URIs.

Counseling Patients on Inhaled Insulin. A comprehensive *Medication Guide* is provided with Exubera. Patients should understand all the information before beginning therapy. A summary of these points, which pharmacists may use in their counseling, is provided in Table 2.

Overview and Summary

The benefits of intensive insulin therapy have been demonstrated in large clinical trials. Despite such advantages, intensive insulin therapy is not widely accepted because of real or imagined barriers to invasive insulin. Inhaled insulin is a non-invasive method of supplying insulin that should alleviate some of the problems and/or fears associated with insulin injections. It has demonstrated efficacy in terms of achieving significant attainment of HbA1C targets in both type 1 and type 2 disease. Inhaled insulin is, therefore, a suitable alternative to injectable insulin to promote achievement of good glycemic control, and therefore help to prevent the microvascular, macrovascular, and neuropathic complications of diabetes and decrease the risk of premature death.

Once inhaled insulin is made available, it may be of particular benefit in patients who are unreceptive to multiple daily insulin injections. It represents a promising and novel diabetes therapy that offers the benefit of noninvasive administration, along with a time-action profile that combines the advantages of both rapid-acting insulin analogs and regular human insulin.

Continuing Education Quiz

This month's questions are taken from the article on "A New Era in the Management of Diabetes: Inhaled Insulin". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 4/15/09. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-06-004-H01.

Name_____

Address_____

City, State, Zip_____

Daytime Phone_____

Date Completed _____
(*Required*)

The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education for pharmacists.

1. All of the following are rapid-acting insulin analogs EXCEPT:
   a. aspart.
   b. glargine.
   c. glulisine.
   d. lispro.

2. With a fasting plasma glucose (FPG) test, the lowest level that defines diabetes is:
   a. 26 mg/dL.
   b. 99 mg/dL.
   c. 126 mg/dL.
   d. 199 mg/dL.

3. Which of the following is a marker of insulin resistance and an independent risk factor for cardiovascular disease?
   a. Hyperinsulinemia
   b. Hypoinsulinemia
   c. Hyperglycemia
   d. Hypoglycemia

4. All of the following statements about Exubera are true EXCEPT:
   a. it is a dry powder formulation.
   b. it is recombinant (rDNA) human insulin.
   c. it comes in a blister pack to be used in combination with an inhaler device.
   d. it comes in five dosage strengths.

5. Compared to injectable insulin, the dose equivalence of Exubera is about:
   a. three times greater than that of injectable insulin.
   b. three times less than that of injectable insulin.

6. The onset of action of Exubera is:
   a. faster than that of regular human insulin.
   b. slower than that of regular human insulin.

7. The primary mechanism of insulin absorption across the alveolar capillary and epithelial cells is:
   a. active transport.
   b. iontophoresis.
   c. passive diffusion.
   d. unknown.

8. Following inhalation, pulmonary delivery of insulin results in peak insulin levels within:
   a. 1 to 5 minutes.
   b. 15 to 20 minutes.
   c. 30 to 35 minutes.
   d. 40 to 45 minutes.

9. Which of the following OTC medicines has a warning on its label advising persons with diabetes not to take them unless directed by a doctor?
   a. Antihistamines
   b. Decongestants
   c. Expectorants
   d. Laxatives

10. Unopened blisters of Exubera should be stored:
   a. in the freezer.
   b. in the refrigerator.
   c. at room temperature.

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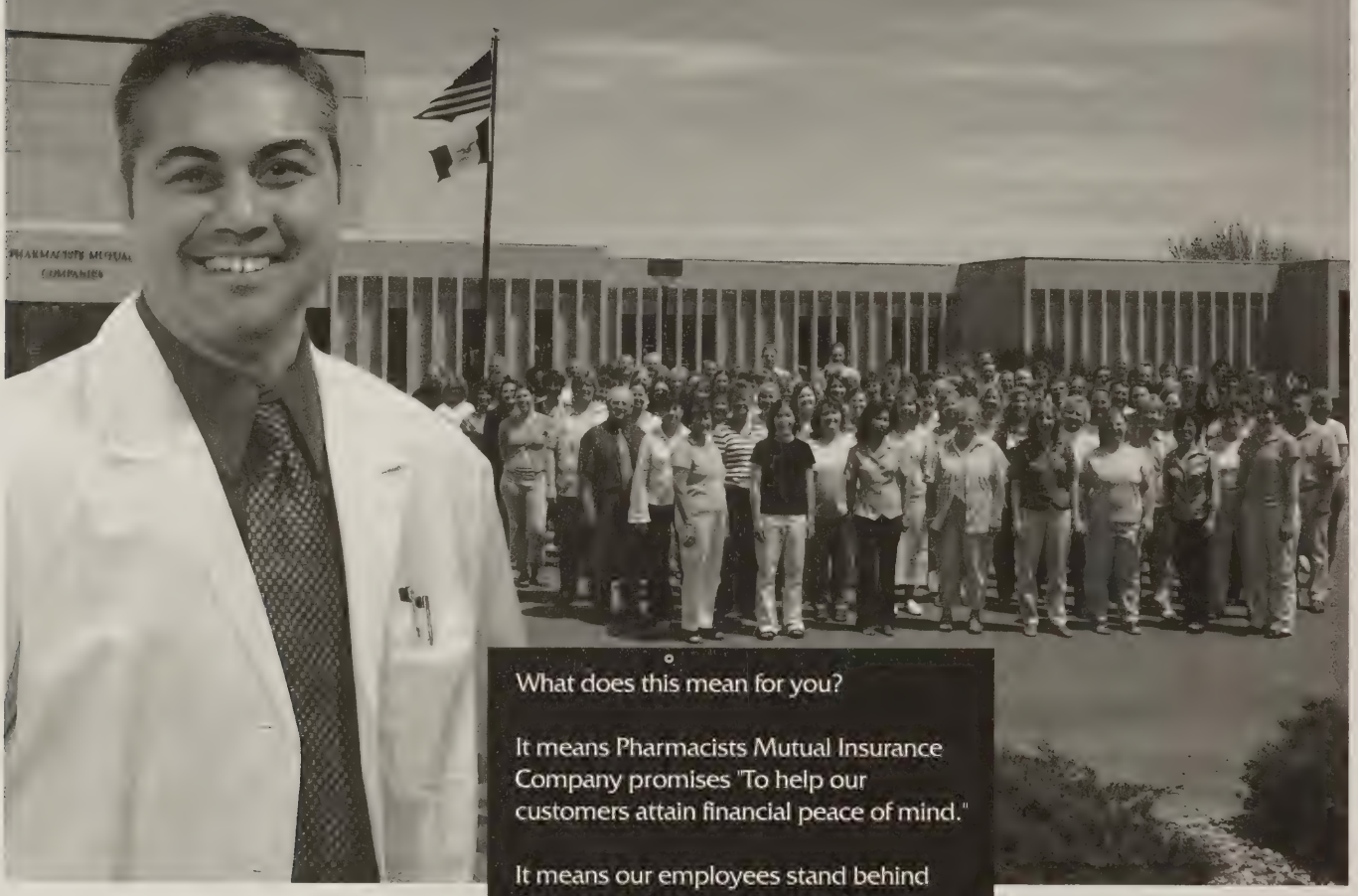

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MARYLAND
Pharmacist
VOLUME 83 NO. 1

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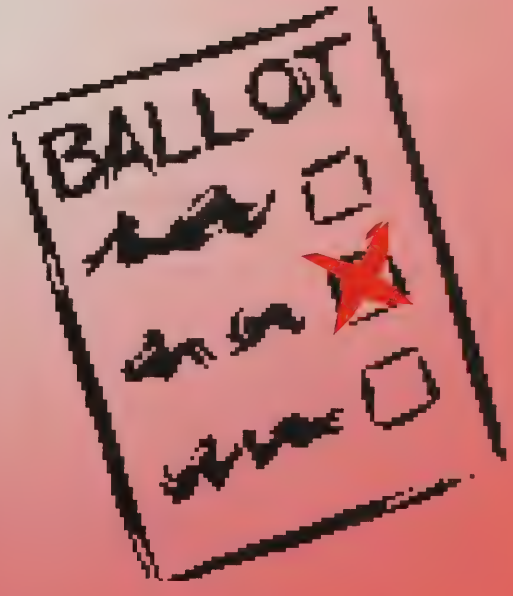
"Off to a Great Start for 2007"

Candidate Statements
"Official Ballot"

Recognizing Pharmacy Excellence
"The 2007 MPhA Awards"

Continuing Education
"Acute Viral Hepatitis: Prevelance, Prognosis, and Prevention"



MARYLAND PHARMACISTS ASSOCIATION
JAN./FEB./MAR. 2007

Maryland Pharmacists Association

650 W. Lombard Street
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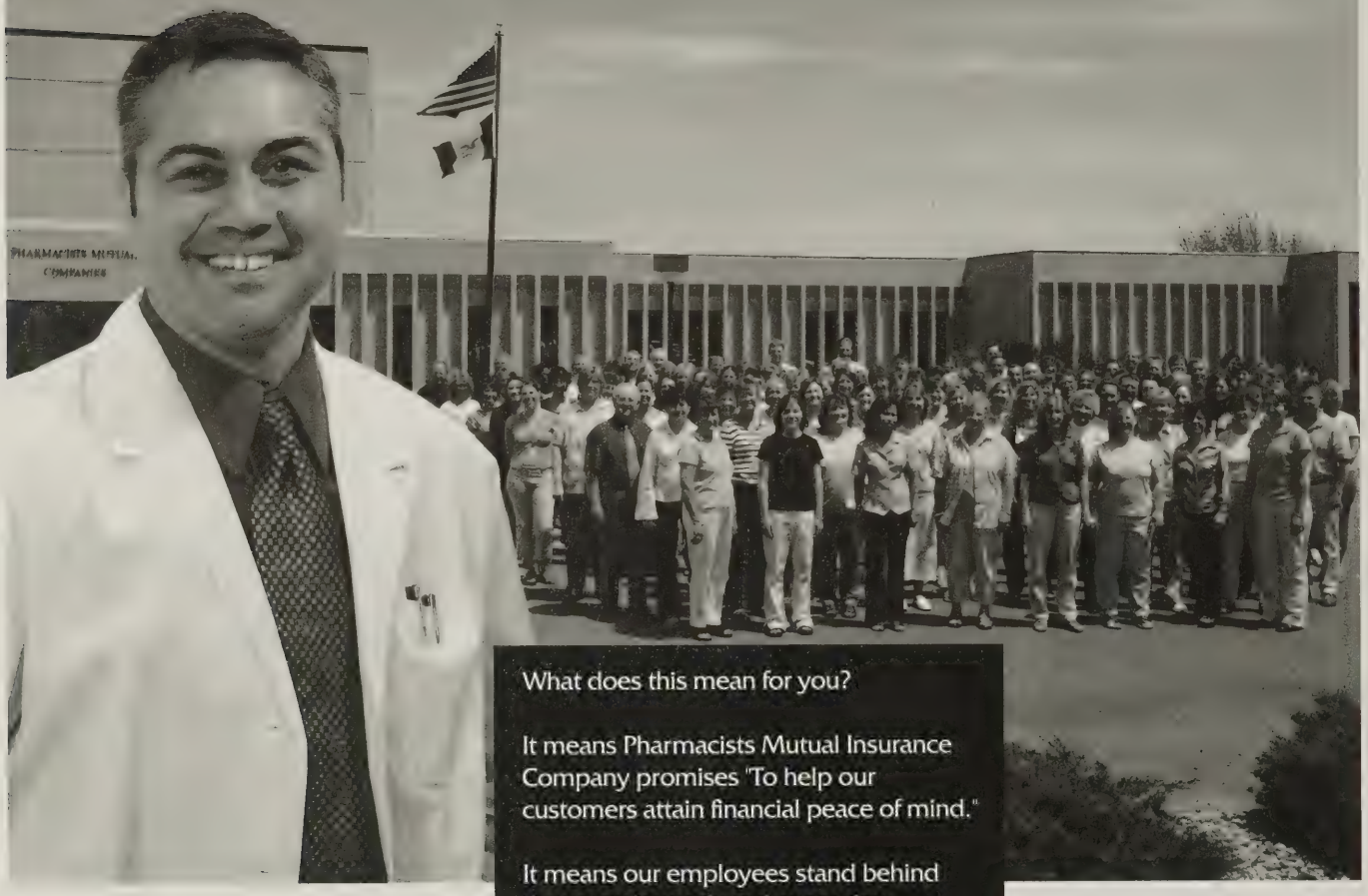

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Presidents' Commentary

Virginia Apyar, President pictured in the lower level of the B. Olive Cole Pharmacy Museum

The Maryland Pharmacists Association is off to a great start for 2007. On Sunday, January 28, 2007 the Mid-year Meeting was held at the Sheraton Hotel in Columbia. There was a dramatic increase in attendance compared to years past .The thought was we might even have to find a larger meeting space in the future. Thanks to the undaunted efforts of Howard, Elsie and Nancy, the day was flawless. What made the Mid-year so great was the line-up of speakers that our Chairperson, Doris Voigt, arranged. Thank you Doris! Doris also served as the meetings official photographer. Her work can be seen on the website click on snapshots. The networking the day provided was evident when Howard tried to get the attendees back into the meeting room after scheduled breaks and lunch. He did manage to keep the day on schedule.

Our corporate sponsors were visible in the exhibit area. As you walked along the mini trade show, you noticed someone was missing. That someone was BIG PHARMA. The days of the large drug companies being association sponsors are sadly over. While we can still apply on-line to get an educational grants, that is also getting more difficult. While all state associations struggled when big pharma no longer was able to provide speakers for CE programs, MPhA was in a unique position and we were able to adapt. What made of transition easier—our relationship with the University of Maryland, School of Pharmacy and its faculty. When a faculty member presents, either at the mid-year or convention, they are always a draw that fills the room. This year we reached out to the U.S. Public Health Service to present and no one was disappointed. We hope they will continue to be a part of the mid-year and the convention.

More good news is the success of Legislative Day 2007. On February 07, 2007 the Maryland Pharmacy Coalition (MPC), which MPhA is a member, had its first dinner CE on current legislative issues. The goal of this CE program was to educate pharmacists on the current issues and how to present them to their legislators in Annapolis. The response again was overwhelming. Over eighty pharmacists attended. Pharmacists are now a voice to be heard in Annapolis. I hope more MPhA members will be in Annapolis in 2008!

One of the best opportunities to come from being president of the association was an invitation to represent pharmacy on the Governor's Workforce Investment Board (GWIB), Healthcare Industry Initiative. I am the only pharmacist on this board. The steering committee I am serving on has been charged with defining healthcare in Maryland. This includes occupations in the healthcare industry and the available workforce that is in the state. The pharmacist shortage is high on the list for the GWIB to focus on. The first healthcare initiative the GWIB focused on was the nursing shortage in Maryland. Industry uses a code system for occupations. This code system from the U.S. Census Bureau is referred to as NAICS (North American Industry Classifications System). I was surprised to learn that pharmacists are not listed separately as were doctors, nurses and dentists. But that we were classified as "other healthcare professionals". I think that is a problem for our profession. At the GWIB we looked at another coding of occupations. The Maryland State Department of Education has created 10 career clusters to help students focus on a career path thus eliminating workforce shortages. Pharmacy is listed separately in career cluster 6 which is titled health and biosciences. Career clusters are used to enhance economic development by providing students a full range of career opportunities to meet the workforce demand thus having an educated, qualified workforce for the state's healthcare industry. Our report should be printed by the end of the year. Solving the pharmacists' shortage won't happen as quickly as we would hope. The efforts of this group will ease the shortage perhaps with a new definition of healthcare which will include wellness care, self care and the careers available.

I am looking forward to seeing everyone at the 125th Convention at the Clarion Resort Fontainebleau Hotel in Ocean City June 16-19, 2007

Ginger

Candidate Statements

Vice President

Candidate Magaly Rodrigues de Bittner, Pharm.D., BCPS, FAPhA
MPhA Trustee- 2000-2007
Chair, Department of Pharmacy Practice and Science
University of Maryland, School of Pharmacy
PharmD- 1983 University of Maryland
BS in Pharmacy- 1979 University of Puerto Rico

It is difficult for me to believe that I have been serving MPhA as a trustee for the past 6 years. As the Chair of the Professional Development Committee, I have been able to promote the development of opportunities for pharmacists to be reimbursed for professional services (the Maryland P3 project is one of the examples of such programs). We have published collaborative practice protocols in the MPhA website, facilitated the delivery of training programs in diabetes and immunization, and provided programming in MPhA meetings for dissemination of opportunities available to Maryland pharmacists. We have been able to advocate and provide leadership on many significant changes in Maryland pharmacy practice that affect pharmacists in all fields of pharmacy. Pharmacists in Maryland have been able to endure (and survive) Medicare Reform and welcome the opportunity that Medication Therapy Management (MTM) has brought to pharmacy. We saw the approval of legislation on collaborative practice and immunization, and most recently the birth of the Maryland P3 project. All of these opportunities have brought pharmacy practice to the forefront and have increased the ability of the pharmacists to impact the health care of Maryland citizens. I have seen our organization grow significantly and become an important voice for pharmacy in Maryland. Together we can continue to grow our professional organization to higher levels.

I am sure that you agree with me that we have come a long way but a lot of work still needs to be done. We must promote business models to help all Maryland pharmacists take advantage of these opportunities. We must deal with the pressures of increased prescription volume, shrinking profit margins, and a shortage of pharmacists. We must become a proactive organization that seeks to create change and provide members with the resources necessary to maximize their contributions to the health care team.

I believe that the Maryland Pharmacists Association is in a great position to continue to address the issues facing pharmacy in the state. I would be honored to serve you, my colleagues, as the president of this organization and contribute to advancing pharmacy practice in Maryland. I will dedicate my time and energy to assure that MPhA continues to be an agent of change and represents the needs of the Maryland pharmacists and pharmacy technicians. I am, in fact, honored to be a pharmacist and would be even more honored to earn your vote to become MPhA president. Let's work together for our profession, pharmacy. Thank you for your support!

Candidate Carol Stevenson, Pharm.D.
I am honored to be nominated for the position of vice president of MPhA. I am a 1970 graduate of the University of Kansas and a 2003 graduate of the University of Maryland Non-Traditional Pharm.D. program. During my career, I have had the opportunity to practice in military hospitals in Maryland and overseas; in civilian hospitals, and in the retail setting at Medicine Shoppe and at Metro Food Markets. I am presently the manager of NeighborCare Pharmacy at Oakcrest Retirement Community. Being a trustee of the Maryland Pharmacist's Association for the past term has been a privilege for me. I have found the organization to be a great advocate for the entire profession of pharmacy. I believe that the Maryland Pharmacist's Association is one of the best organizations to enable pharmacists to contribute to their profession and to those they serve. MPhA honors the past with our wonderful building and museum; looks to the future by developing student involvement and leadership; embraces technicians as vital colleagues; encourages new initiatives such as the P3 project and Medication Therapy Management; supports the Maryland Pharmacy Coalition; and provides

excellent educational opportunities for both members and non-members. I would be most honored to serve MPhA as vice president.

Trustee Seat 1

Candidate Kristen Fink, Pharm.D.
Since I joined MPhA I have had the great opportunity to participate not only in the professional development committee but in the heart of Maryland pharmacy. It is my sincere desire to serve on the Board of Trustees and work to strengthen and promote the profession of pharmacy as well as further the growth and potential of all pharmacists in the state of Maryland.

As a clinical pharmacy specialist for Kaiser Permanente I have a strong background in disease state management, Medicare Part D Medication Therapy Management, and drug use optimization. A graduate of Duquesne University, I am now a student preceptor for six pharmacy schools and make it my top priority to show students the wide array of opportunities available to them. One of my passions is patient safety; I have designed several projects that have been successful in reducing medication errors both in the Pittsburgh hospital where I interned and in the managed care setting. As the daughter of an independent pharmacist here in Baltimore, I have worked in the retail setting since age 16 and have an in depth knowledge of the great potential and challenges that retail pharmacy faces everyday.

I believe that the emerging opportunities in collaborative practice and medication therapy management are changing pharmacy as we know it. Not only are we recognized by our peers and patients for our ability to help manage their health, we now have the potential to be reimbursed for the knowledge we have to offer. I am proud to say that I have just submitted my application to become the first independent pharmacist in the state of Maryland to implement a collaborative practice agreement, partnering with a local physician. This collaborative practice model is already a success in my current practice at Kaiser Permanente and my goal is to use my knowledge and experience to help make this model a reality for every interested pharmacist. I believe that my varied background and knowledge base will allow me to contribute a great deal to the Board of Trustees for MPhA as well as the pharmacy profession as a whole. I hope that you will give me the opportunity to contribute my enthusiasm and drive to the MPhA Board of Trustees.

Candidate Brian Hose, PharmD
I am honored to be nominated for my first elected position within MPhA and am excited to continue my service to the organization. I have worked in Community Pharmacy for the past 3 years and specifically for Independent Epic Pharmacies since 2005. I am a 2006 graduate of the University of Maryland School of Pharmacy and since graduation have been employed as a Staff Pharmacist at Boonsboro and Sharpsburg Pharmacies, located in Western Maryland. I am also a member of the P3 Pharmacist Network and currently work in the Cumberland pilot program counseling diabetic patients.

For 2006-2007, I was selected as MPhA's appointee to the Maryland Pharmacy Coalition (MPC). This appointment has allowed me to stay involved in an organization that I feel is becoming increasingly important to our profession as we learn the value of Pharmacy's voice in the legislative process. I served as the MPC Chairman in 2005-2006 where I helped develop our Pharmacy Month supplement published in the Baltimore Sun and our Legislative Initiatives in Annapolis. This year I took on the responsibility of chairing MPhA's Legislative Committee and at the time of this statement am busy preparing for another successful year lobbying our legislative leaders. I continue to be involved with the School of Pharmacy and have been active in the Alumni Association since graduation.

I am dedicated to protecting the viability of our profession whether through lobbying efforts in Annapolis and Washington or new and innovative pharmacy practice initiatives. Thank you for your consideration and I look forward to my continued service to MPhA and our profession.

Trustee Seat 2

Candidate Neil Leikach, RPh

I have been a trustee for 1 term and would like to be reelected to the board for another term. I graduated from Maryland in 1992 and have been active in MPhA, NCPA and the alumni association since then. As an owner of 3 independent pharmacies in the Baltimore area, I have seen how state and federal legislation has change the way we practice community pharmacy. As a group,MPhA, can help steer pharmacy in the right direction and continue to show Marylander's what our profession is all about. Thank you for your consideration.

Candidate Scott Vehovic, R.Ph.

As a 1996 graduate of Duquesne University, I'm currently the district pharmacy supervisor for the Walgreen Company in Baltimore and have practiced the profession of retail pharmacy here in Maryland solely for almost eleven (11) years. The obstacles to our profession have changed since then, however our role as providers has not. The education, knowledge, and skills we possess make our jobs as pharmacists vital to the future of healthcare and pharmacy. The strength of the MPhA is dependent on the sharing of information we have gained through our experiences. I am honored to be nominated as a Trustee and as a current MPhA member, my primary goal has always been to use my knowledge and experience to improve patients' lives while at the same time reduce the costs of healthcare in Maryland. In the future we will play a more proactive role, ensuring patients use their medications correctly through MTM and other clinically based programs. It is this synergy between patients and pharmacists that makes the practice of pharmacy a total healthcare package versus a commodity. I appreciate the opportunity to represent all Maryland pharmacists practicing in this endeavor.

A basic philosophy of Dr. John C. Krantz Jr. was "...knowledge of the history of a science is essential to an intelligent understanding of it."

A basic philosophy of Dr. John C. Krantz Jr. was "...knowledge of the history of a science is essential to an intelligent understanding of it." Close friends and colleagues of Dr. Krantz have stated that he had an encyclopedic knowledge that covered a wide field of experimental and clinical medicine. He served thirty-three years as professor of pharmacology at the University of Maryland, School of Medicine. The son of a Maryland pharmacist, Dr. Krantz graduated from the University of Maryland, School of Pharmacy in 1919. He had the privilege of attending the pharmacy school while Dr. E. F. Kelly was dean. With all his scientific contributions too numerous to list, some important ones still used today include isosorbide dinitrate and theophylline. At the time Dr. Krantz wrote his book Historical Medical Classics Involving New Drugs (1974), very few oral agents were available to treat diabetes mellitus. An important concept one can take from the book, and from the developments since its print, is that medical science is always changing and evolving.

The treatment of diabetes mellitus is starkly different today then the treatment of the 1960's. A striking example is the limited choice of oral diabetic agents over four decades ago. Only two different classes of oral diabetic agents were available compared to the six classes today. Tolbutamide (Orinase®), chlorpropamide (Diabinese®), tolazamide (Tolinase®), acetohexamide (Dymelor®), all sulfonylureas, and phenformin (DBI), a biguanide, completed the list of oral diabetic agents in the 1960's. Phenformin was eventually taken off the market in 1977 due to cases of fatal lactic acidosis. First-generation sulfonylurea use has since declined due to the introduction of second-generation sulfonylureas that includes glyburide (Diabeta ®, Micronase®), glipizide (Glucotrol®), and glimepiride (Amaryl®). Glyburide and glipizide were first introduced in 1984, followed by glimepiride in 1996.

(Continued on page 11)

2007 Maryland Leadership Elections
Official Ballot

Please select the candidate you believe will best fulfill the duties of the office by checking the box appearing beside their name.

Maryland Pharmacists Association Officers

Vice President

□ Magaly Rodrigues de Bittner, Pharm.D. □ Carol Stevenson, Pharm.D.

Please select the candidate you believe will best represent you as a member on the Board of Trustees by checking the box appearing beside their name.

Maryland Pharmacists Association Board of Trustees

Trustee Seat # 1

□ Kristen Fink, Pharm.D. □ Brian Hose, Pharm.D.

Trustee Seat # 2

□ Neil Leikach, R.Ph. □ Scott Vehovic, R.Ph.

When completed, seal and return your self-mail ballot to the Maryland Pharmacists Association, ***received by Friday, May 4, 2007***. For questions, please call MPhA at 800-833-7587.

Fold

2007 Maryland Leadership Elections
Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

Fold

(Continued from page 8)

The introduction of second-generation sulfonylureas represented advancement in the treatment of type 2 diabetes mellitus (T2DM). The newer compounds were approximately 100 times more potent and effective at lower doses. Second-generations were less likely to produce side effects/and or drug interactions, and thus their use is preferred over first-generations. Sulfonylureas work to lower fasting plasma glucose (FPG) by increasing the release of insulin from functioning pancreatic β-cells. The major adverse effects include hypoglycemia and weight gain. Hypoglycemia was more prevalent with first-generations due to their relatively long half-lives.

The 1990's saw marked advances and changes in the treatment of T2DM. Three new classes of drugs were introduced and a new biguanide, metformin, was made available. Metformin, although in clinical use for over four decades, was not available in the U.S. until 1995. Its primary mechanism is to decrease hepatic gluconeogenesis. The incidence of lactic acidosis is minimal, 0.03 per 1000 patient-years, and since it does not affect insulin secretion, metformin does not cause hypoglycemia. Added benefits of metformin include a small reduction in LDL and modest weight reduction. The new classes of drugs included α-glucosidase inhibitors (AGI), thiazolidinediones (TZD), and nonsulfonylurea secretagogues.

AGIs became available in 1996 and include acarbose (Precose®) and miglitol (Glyset®). AGIs work by reducing postprandial glucose levels by slowing intestinal absorption of carbohydrates. For this reason, acarbose and miglitol should be taken with meals. Like metformin, AGIs do not produce hypoglycemia, but have no affect on LDL levels. GI disturbances (abdominal pain, diarrhea, flatulence) are the most common adverse affects which can be minimized by slowly titrating doses. TZDs, troglitazone (Resulin®), rosiglitazone (Avandia®), and pioglitazone (Actos®), were first marketed in 1997. TZDs work by improving insulin sensitivity in muscle and adipose tissue and secondarily by decreasing hepatic glucose production. This class requires the presence of insulin to work. Along with the intended benefits of new drugs, there are also unwanted adverse effects. Troglitazone was removed from the market by the FDA in March 2000 due to hepatotoxicity. Rosiglitazone and pioglitazone do not share this same hepatotoxicity profile, but caution should be taken in hepatic impairment. Common side effects include edema and weight gain and there is no risk of hypoglycemia.

In 1998, the nonsulfonylurea secretagogues were introduced. They include repaglinide (Prandlin®) and nateglinide (Starlix®). When glucose is present, these agents stimulate insulin release from functioning pancreatic β-cells. Due to short half-lives, stimulation of insulin release is short, which reduces the risk of hypoglycemia and weight gain. These drugs are dosed prior to meals and are useful in patients with high postprandial glucose levels. Proving that medical science is always changing, another new class of drugs for treating T2DM was introduced in late 2006. Sitagliptin (Januvia®) was the first dipeptidyl peptidase 4 inhibitor (DPP-4) to be marketed. It protects endogenous incretin hormones. Simply speaking, sitagliptin enhances the body's own ability to lower blood glucose when it is elevated. Headache, upper respiratory infections, and nasopharyngitis were common side effects and hypoglycemia was seen in 1.2% of patients. This is comparable to placebo.
So, what's next? Mitaglinide, a nonsulfonylurea secretagogue, is in phase II trials. Novartis is expected to release its DPP-4 inhibitor vildagliptin (Galvus®) in early 2007. Another new class is currently in clinical trials for treating T2DM, the glucokinase (GK) activators. GK is found in the liver and controls hepatic glucose metabolism and influences glucose uptake and production. It appears the evolutionary trend of treating T2DM will continue.

Koski RR. Practical Review of Oral Antihyperglycemic Agents for Type 2 Diabetes Mellitus. The Diabetes Educator. 2006;32(6):869-76.

Skaer TL, Sclar DA, Robison LM. Trends in the Prescribing of Oral Agents for the Management of Type 2 Diabetes Mellitus in the United States, 1990-2001. The Diabetes Educator. 20

Recognizing Pharmacy Excellence
The 2007 MPhA Awards

Each year, the Maryland Pharmacists Association recognizes professional excellence through a series of awards. To nominate a pharmacist for one of the awards described below, complete the Official Award Nomination Form. The forms should be submitted to: Award Nominations, c/o Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572.

All nominations will be reviewed by the Past Presidents Council who is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the award's presentation at the 125th Annual MPhA Convention.

For consideration, all nominations must be received no later than ***Friday, April 6, 2007.***

- **Pharmacists Mutual Distinguished Young Pharmacist Award**
  Awarded to a pharmacist who graduated within the past ten years and has made a significant contribution to the profession through service to a local, state or national pharmacy organization. ***Who is Eligible:*** Any MPhA pharmacist member who graduated from pharmacy school in 1997 or after.

- **Maryland Pharmacists Association Honorary President**
  An honorary position on the Board of Trustees given to a person, not necessarily a pharmacist, who has worked for the MPhA or Maryland Pharmacy over a long period of time. ***Who is Eligible:*** Any long standing contributor to the profession or the Association.

- **MPhA Mentor Award**
  This award recognizes individuals who encourage pharmacists, technicians, and/or student pharmacists in the pursuit of excellence in education, pharmacy practice, service, and/or advocacy. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the Award.

- **Seidman Distinguished Achievement Award**
  Created to honor the major impact on the pharmacy profession by Henry Seidman, this award is presented for outstanding service by a Maryland pharmacist to the pharmacy profession during *either* the past year or over a period of years. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the award.

- **Wyeth-Ayerst Bowl of Hygeia Award**
  The Bowl of Hygeia recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions. ***Who is Eligible:*** Any MPhA member pharmacist who has not already received the Bowl of Hygeia.

- **Elan Innovative Practice Award**
  Established in 1993, this award aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. Any practicing pharmacist member within the geographic area who has demonstrated innovative pharmacy practice resulting in improved patient care. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the award.

Maryland Pharmacists Association
Award Nomination Form

To nominate a Maryland pharmacist for one of MPhA's annual "Recognizing Pharmacy Excellence" awards, this form must be completed and returned to the Maryland Pharmacists Association no later than ***Friday, April 6 , 2007***. All nominations will be held in strictest confidence by the MPhA Past Presidents Council, which is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the presentation of the award.

Please consider the following nominee for:

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Attach a current resume or curriculum vitae for the nominee that shows their professional and personal achievements. This information is essential for the Past Presidents Council to make its decisions as to which candidates will be recipients of the "Recognizing Pharmacy Excellence" awards. In addition, the nominator should attach a brief letter explaining why the nominee is worthy of receiving this award.

Return the completed form to:

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Screening and Intervening on Medication Related Problems of Older Russian Americans in Baltimore City

Tatiana N. Kondrakhina Pharm.D. Candidate

During the summers of 2005 and 2006, I was involved in a geriatrics focused project with Dr. Brandt, Associate Professor, Geriatric Pharmacotherapy and Dr. Julie Caler, Geriatric Pharmacotherapy resident. The project involved screening and intervening on medication related problems of older Russian Americans in Baltimore City. The results of this effort hopefully will have positive impact on understanding and improving pharmaceutical care for the population of older adults who cannot speak English.

Patients were screened for identification of medication related problems utilizing the medication risk questionnaire that was translated into Russian. The survey was performed during the home visit with a Senior Friendly community health nurse, Miriam Rossman. During the summer of 2005, the project was paired with the Vial of Life program, which was designed to assist emergency rescue teams in medical treatment in the event that a patient is unable to communicate. During the summer of 2006, the project was paired with project LIGHT at Levindale Hebrew Geriatric Center and Hospital, coordinator Veronica Poklemba, APRN-PMH. The goal of LIGHT was to screen the Russian speaking elderly patients for depression.

There were 64 patients screened during the Vials of Life Session with 64% of the participants taking five or more medications and 72 % had three or more medical problems. Even though only 16% of patients acknowledged having difficulty following their medication regimen, many patients had expired medications at home and could not recall how often they take their medications. The patients who had difficulty following their medication regimen were living alone, were older than 70 and had evidence of cognitive impairment. Interestingly, only one patient out of seven was willing to have her/his medications reviewed by a pharmacist. The language barrier, poor condition of health, and a distant relationship with medical professionals may explain this phenomenon. Consults were developed and shared with the patients and if applicable their respective healthcare professionals. There were follow-up appointments with patients to evaluate the implementation of the consults.

The translation of medical information into Russian and explanation of the goal of Vial of Life program was performed parallel with the medication related problems survey. The form with important medical information was placed in a small prescription vial, which was stored in the refrigerator. Red stickers on the entry door and the refrigerator were placed to help the paramedics to quickly find the critical details necessary to help the patient. This program is crucial for the Russian speaking elderly population who cannot communicate with emergency rescue teams in English and are at a high risk for health-related emergency situations.

The translation for the screening interview to identify patients with depression was performed during the LIGHT project. There were a total of 27 patients screened using the Geriatric Depression Scale translated to Russian. Six patients with signs of depression were identified. All identified patients agreed to start counseling and were scheduled to see a psychiatrist at Sinai Hospital.

Conclusions:

As a student pharmacist, I learned quite a few things during this experiential course. All in all I felt that:

- Personal contact was much better than telephone: patients were more open to answer questions, and more willing to meet again.
- The patients may in reality take more medications than they report during a survey. During a home visit, they showed more medications than they mentioned in the questionnaire.
- The parallel participation in Vial of Life program was very helpful for filling out the Medication Risk Questionnaire because the senior citizens perceived that they were receiving a benefit in exchange for their time.
- All screened patients with depression live alone or have a sick spouse at home. Some patients had poorly controlled symptoms such as pain or high blood pressure.
- Many patients with signs of depression had been taking antidepressants in the past, but only when they felt extremely depressed. The patients

reported stopping medications due to a having to take multiple medications.

- Most of the patients felt uncomfortable discussing their mental health problems due to stigma related to seeking professional help.
- Many patients utilize traditional herbal and supplemental products, the contents of which may be unknown to the primary health care provider.
- The process of impairment of memory and mental abilities may be troubling for an older adult with a good level of education and a highly intellectual job in the past. They may refuse to take medications or use assistive devices because they do not want to feel old and helpless.
- Many Russian speaking patients were dismissing their health problems as an inevitable part of aging that did not warrant medical attention. Some patients with poorly controlled symptoms were unwilling to share their problems with their physicians. They did not want "to waste the doctor's time" with concerns they think their doctor will consider unimportant.

It is extremely important especially for older Russian American individuals to see their health provider regularly and bring all of their medications to the doctor's office for review. In addition, it is vital that pharmacists assist with medication lists that should accompany the patient at all times. The results of this project demonstrate the many factors and challenges that can complicate the provision of pharmaceutical care to elderly patients of different cultures and languages.

"Therapeutically Speaking..."
Counterfeit Drug Products: Problem and Solutions

Mrs. Harrity is a long-time patient who arrives for her bi-monthly refills of hydrochlorothiazide and glyburide. "Do you know if there has been a problem with fake Lipitor?" she asks. In speaking with her, you learn that she has been obtaining Lipitor from what she describes as an on-line Canadian pharmacy, to treat hypercholesterolemia. She states, "The tablets have not looked the same and now my cholesterol is up 70 points from 190 to 260".

Counterfeit drugs are any brand name or generic product sold under a product name without proper authorization.[1] While this definition includes product that has been relabeled or repackaged without authorization, most important to patient health are counterfeits that contain incorrect drug, no drug, improper dose, and/or contaminants. Risks involved with taking a counterfeit drug include unexpected side effects, allergic reactions, and the worsening of their medical condition.

Counterfeit drug products within the U.S. drug supply chain are a potentially serious public health concern, although the scope of this problem is not known. In the U.S, the prevalence of counterfeit drugs from community pharmacies is thought to be less than 1%. Estimates of the prevalence of counterfeit medicines worldwide range from 5-10% generally, and up to 50% in select countries.[2] FDA investigations suggest that the number of counterfeit drugs within the U.S. is increasing. Through the 1990's, the FDA investigated an average of five counterfeit drug cases per year. This number has sharply increased to over 20 cases per year since 2000, prompting the FDA to issue a report in 2004.[3] The FDA more recently reported the initiation of 58 counterfeit drug cases, representing an almost doubling of cases since 2003. However, this increase may be due to increased vigilance by and coordination among manufacturers, distributors, re-packagers, pharmacies, patients, and regulators.

Multi-Pronged Approach

The FDA has outlined a multi-pronged approach to limit counterfeiting and has provided comment on progress to date.[3,4] The seven areas of improvement are: a) securing the actual drug product and its packaging, b) securing the movement of the product as it travels through the U.S. drug distribution chain, c) enhancing regulatory oversight and enforcement, d) increasing penalties for counterfeiters, e) implementing secure business practices, f) heightening vigilance and awareness of counterfeit drugs, and g) increasing international collaboration. While internet pharmacies located outside the U.S. are a potential source for introducing unapproved and counterfeit drugs into the U.S., the FDA report does not address international internet pharmacies or the illegal re-importation of medicines into the U.S., since these avenues are formally not part of the U.S. drug supply chain.

Technology is playing a central role in the efforts to secure product, packaging, and movement through the supply chain, via a combination of track and trace technologies and product authentication technologies. The FDA encourages the use of one or more authentication technologies for drug products, especially products with greater potential to be counterfeited. Authentication technologies include color-shifting inks, holograms, taggants, and chemical markers that can be imbedded in a drug or its label. In addition, these technologies also have the ability to detect "gray market" products. "Gray market" products are those that are sold by a manufacturer at a relative discount to a buyer (e.g. hospital), but which is subsequently sold to a third party who would not receive the same discount from the manufacturer. The gray market stems from preferential product pricing for some customers, compared to other customers.

Since individual states license distributors and pharmacies, state boards of pharmacy can play a critical role in implementing increased regulatory oversight. The Healthcare Distribution Management Association (HDMA) has suggested strengthening licensing procedures to consider that a legitimate drug wholesaler is structured as a "going concern," demonstrates financial responsibility, and possesses robust operational standards and

demonstrable compliance histories. It has also been suggested that manufacturers and distributors only sell to authorized distributors and licensed providers, and that authorized distributors only purchase from manufacturers or other authorized distributors. It has been further suggested that manufacturers assume greater responsibility for product integrity in the supply chain.

Authentication Technologies for Packaging

Radio frequency identification (RFID) is one of the leading package authentication technologies. RFID is the technology in Maryland's EZ-Pass highway toll collection system, allowing drivers to save time when driving over the Chesapeake Bay Bridge. The FDA has indicated that RFID is the most promising track and trace technology. Track and trace would yield an accurate drug "pedigree" to document that the drug was manufactured and distributed under secure conditions. The Pharmaceutical Research and Manufacturers of America (PhRMA) White Paper supports electronic technologies, such as two-dimensional bar codes and RFID tags, allowing real-time authentication at the dispensing location.

A misunderstanding of RFID is the notion that anybody can read an RFID tag, such that anyone could figure out what prescriptions a patient is carrying with them as they leave the pharmacy. As provocative as this scenario sounds, this scenario would not be the case with RFID, or at least highly unlikely. Does anyone worry about their EZ-Pass tag being read by a would-be-thief, while their car is parked at work ? No, and patients would not have to worry about RFID broadcasting what medicines they are taking. First, a drug RFID tag on a bottle of 100 tablets would be separated from the dispensed tablets. Second, an RFID tag for a drug only encodes for a series of numbers and letters, and would only have meaning if connected to product identity, which would be a challenge.

Product Authentication

A disadvantage of authentication technologies for packaging, such as RFID, is that they only provide information about the packaging, which may not be indicative of what is actually inside the package. Yes, authentication of packaging is probably the best that can be achieved by wholesalers, who operate at low financial margins and practically never open packages. However, as an "end of the line" check, product authentication by pharmacists has great potential for being a final confirmation of product identity. Product authentication technology also holds promise to minimize dispensing errors.

One promising technology is near infrared (NIR) spectroscopy, or simply NIR. NIR has been demonstrated to rapidly, in real time, identify medicines, without destroying or harming the medicine. Analytical Spectral Devices, Inc. has developed the RxSpec® technology which utilizes NIR to directly check the prescription drug while in the dispensing vial. This real time measurement is sensitive to chemical composition, color, and dosage level. The measured "chemical fingerprint" is compared to a known database, thereby providing 100% assurance that the dispensed drug is correct in both type and dose/concentration. Currently, the system is used in central-fill and mail-order pharmacies. Prescription vials that are filled, but uncapped move within an RFID-tagged carrier that pauses under the RxSpec® NIR camera. The RxSpec® system then collects an NIR image, as well as reads the RFID tag in the vial's carrier. The system queries a database for the NIR image of the drug that should be in the vial. A pass/fail result is recorded and later displayed to the pharmacist at the final inspection station.

Professor Stephen Hoag and I at the University of Maryland are developing NIR technology that would allow pharmaceutical manufactures to encode each lot batch of medicines. Each batch of product, such as Lipitor, would be made unique by incorporating slight tablet formulation changes, compared to the previous batches. The unique formulation would provide for a "spectral signature" that is invisible to the naked eye, but readable by an NIR camera.

View of Tomorrow

The primary barriers of implementing anti-counterfeit technology are not technological in nature, but lie in the fact that manufactures, distributors, and pharmacists must work together to protect the entire drug distribution system. Pharmacists have of course always played a leading role in assuring that the right patient gets the right drug at the right time. However, the different and sometimes conflicting interests of manufactures, distributors, and pharmacists does create significant barriers to the implementation of new technologies. These barriers won't be overcome without significant effort and participation of all these different groups. At this point, it appears that counterfeit drug products are a small but growing problem in the US, but that it is in everyone's best interest to continue to work together to secure an even better drug distribution system.

Back to Mrs. Harrity's question, her cholesterol increase may in fact be due to taking a counterfeit form of Lipitor. She should consider having this prescription filled along with her hydrochlorothiazide and glyburide at her local pharmacy.

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James E. Polli, RPh, PhD
Associate Professor, University of Maryland School of Pharmacy
jpolli@rx.umaryland.edu

Column Editor:
Mary Lynn McPherson, Pharm.D., BCPS
Professor, University of Maryland School of Pharmacy
mmcphers@rx.umaryland.edu

AND THE LAW

By Kerianne M. Hanson & Don R. McGuire, Jr., R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

COMBAT METHAMPHETAMINE EPIDEMIC ACT:

WHAT THIS ACT MEANS FOR YOUR RETAIL SETTING

On March 9th, 2006, President Bush signed the Patriot Act, which includes a portion known as the Combat Methamphetamine Epidemic Act of 2005[1]. In light of this decision, the sale of pseudoephedrine-containing products across the nation is set up for big changes, and the responsibility of enforcing these changes has landed on the shoulders of licensed pharmacists in retail settings.

Pseudoephedrine is a decongestant found in multiple products used to treat symptoms associated with the common cold and seasonal allergies[2]. It is also the primary ingredient needed to manufacture methamphetamine, an illicit drug that has rapidly gained popularity in the U.S. over the past few years. The new regulations regarding the sale of pseudoephedrine are intended to curb the manufacturing of methamphetamine by making it more difficult to accumulate large amounts of pseudoephedrine and by keeping a record of all pseudoephedrine purchases.

The Combat Methamphetamine Epidemic Act categorizes pseudoephedrine as a controlled substance and regulates, among other factors, the amount of pseudoephedrine sold to individuals. Although some states, particularly in the Midwest, have been following pseudoephedrine regulations for over a year now, the Combat Methamphetamine Epidemic Act makes the regulations federal law.

Beginning September 30, 2006, patients everywhere in the nation will need to visit a pharmacy or other regulated seller in order to purchase pseudoephedrine-containing products.

It is important to keep in mind that some of the specific regulations, such as who in the pharmacy is allowed to sell the products (i.e. pharmacists only, technicians, interns, etc.) has been left up to the individual states. States may also implement more stringent requirements for the purchase limitations. Pharmacists should check with their State Board of Pharmacy to ensure they are aware of state-specific regulations and train their pharmacy staff accordingly.

Some of the federal regulations regarding the sale of pseudoephedrine-containing products according to the Combat Methamphetamine Epidemic Act are summarized below[3]:

- All pseudoephedrine-containing products must be kept behind the counter.
- An individual may purchase no more than 3.6 grams of pseudoephedrine in one day.
- An individual may purchase no more than 9 grams of pseudoephedrine in any

1 *Legal Requirements for the Sale and Purchase of Drug Products Containing Pseudoephedrine, Ephedrine, and Phenylpropanolamine*. U.S. Food and Drug Administration. Accessed May 24, 2006. www.fda.gov/cder/news/methamphetamine.htm.

2 *Lexi-Comp's Drug Information Handbook*. 13th ed. Hudson, OH: APhA; 2005:1275-76.

3 The Library of Congress. *Title VII: Combat Methamphetamine Epidemic Act of 2005*. House Report 109-333. Accessed May 24, 2006. http://thomas.loc.gov/cgi-bin/cpquery/?&dbname=cp109&sid=cp109djs6R&refer=&r_n=hr333.109&item=&sel=TOC_358801&>

30-day period (however, only 7.5 grams if the seller is a mobile retail vendor).

- The purchaser must present a State or Federal Government issued photo identification card at the time of purchase.
- Either a written or electronic logbook of all pseudoephedrine transactions must be kept by the pharmacy for a period not less than two years from the date of purchase.
- For each sale, information including the name and address of the purchaser, the name of the product, the quantity purchased, and the date and time of the transaction must be collected and entered into the logbook. Many states will also require additional information be collected, such as the purchaser's birthday or a driver's license number.
- Products packaged for individual sale that contain less than 60 milligrams of pseudoephedrine are exempt from the logbook requirements but must also be kept behind the counter.
- The pharmacist must confirm the information provided by the purchaser matches that provided on the identification card.
- The purchaser must provide a signature verifying the information provided is correct.

In response to the new regulations, and in an effort to further hinder methamphetamine production, many product manufacturers have voluntarily re-formulated their products to contain alternative decongestants such as Phenylephrine. These products, commonly identified by the letters PE (ex. Sudafed® PE), may offer alternatives to patients who need decongestant products on a daily basis. It is also important to recognize that the majority of the regulations established by the Combat Methamphetamine Epidemic Act do not apply to prescription products containing pseudoephedrine, but these products will be classified as controlled substances, and regulations set forth by the Controlled Substance Act 1970 are now applicable.

Complete information regarding the Combat Methamphetamine Epidemic Act and the regulations it sets forth are available on the Food and Drug Administration's website (www.fda.gov) and from each individual state's Board of Pharmacy.

© Kerianne M. Hanson and Don R. McGuire. Kerrianne M. Hanson is a Pharm.D/MBA Candidate at the Drake University College of Pharmacy in Des Moines, Iowa. Don R. McGuire Jr., R.Ph., J.D. is Assistant General Counsel, at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

Combat Methamphetamine Epidemic Act:
What This Act Means For Your Retail Setting

This a clarification of Rx and the Law article entitled Combat Methamphetamine Epidemic Act: What This Act Means For Your Retail Setting. The law does not restrict sales to only pharmacies. Sales are restricted to retailers who have undertaken the control and training requirements of the Act. States are also allowed to enact more stringent requirements than the Federal sales limitations. The 30 day sales limitation should have said that individuals are restricted to purchasing no more than 9 grams of pseudoephedrine in a 30 day period. The 7.5 gram limitation applies to sales by mobile retail vendors. We apologize for the inaccuracies.

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Continuing Education for Pharmacists

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Acute Viral Hepatitis: Prevalence, Prognosis, and Prevention

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goals. The goals of this lesson are to discuss acute viral hepatitis with emphasis on the biological characteristics of and physical responses to hepatitis viruses A, B, and C.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. summarize key points relative to the biological characteristics of hepatitis A, B, and C viruses;
2. identify the pathological responses to infection by hepatitis A, B, and C viruses; and
3. select from a list important points to convey to patients relative to acute viral hepatitis.

This continuing education activity is supported by an educational grant from GlaxoSmithKline.

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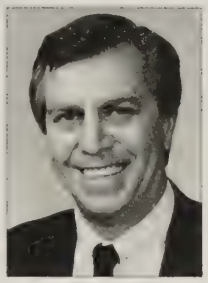
Gossel



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Acute viral hepatitis is a systemic infection of the liver predominantly. Most clinical cases are caused by one of five viruses: hepatitis A virus (HAV), hepatitis B virus (HBV), hepatitis C virus (HCV), hepatitis D virus (HDV), and hepatitis E virus (HEV). Together, they infect nearly 5 million people in the U.S., and according to a World Health Organization estimate, more than 500 million people worldwide.

All human hepatitis viruses are RNA viruses with the exception of HBV, which is a DNA virus. All hepatitis viruses produce clinically similar illnesses ranging from asymptomatic disease to rapidly progressive and chronic liver disease that can lead to cirrhosis and hepatocellular carcinoma. The three viruses that cause most human cases of hepatitis in the U.S. are compared in Table 1.

Epidemiology

Viral hepatitis was formerly labeled either as "infectious" or "serum" hepatitis for HAV and HBV, respectively. Distinguishing between the various viral types cannot be accomplished solely on the basis of clinical or epidemiologic features. Today, classification involves specific serologic testing.

Hepatitis A. HAV is a highly contagious virus that causes widespread human infection worldwide, particularly in developing countries. There are also areas in the U.S., which because of poor sanitation practices, have high HAV infection rates.

The course of hepatitis A infection is extremely variable. The majority of infections in children are asymptomatic, whereas most adult infections are symptomatic. Approximately 100 people in the U.S. die each year as a result of HAV.

HAV is transmitted almost exclusively by the fecal-oral route. Unlike HBV and HCV, the hepatitis A virus remains stable when hepatocytes secrete it into the bile, which passes into the digestive tract. Fecal matter from an infected person, therefore, contains a high concentration of the virus, and it can survive on a hand or other surface for three to four hours at normal room temperatures. The virus can also be transmitted via a contaminated eating utensil.

Person-to-person transmission of HAV is accelerated by poor hygiene and overcrowding. Large outbreaks have been traced to contaminated food, water, milk, and raw shellfish. Spread within families, children and employees in daycare facilities through diaper changing, and persons within institutions including the military and prisons is also common. Kissing on the mouth and anal sex are confirmed routes of transmission. Contaminated needles and/or syringes used for injecting illicit drugs is a route of transmission. It is not known how infection occurs in about 40 percent of reported cases. The Centers for Disease Control and Prevention (CDC) lists household or sexual contacts, daycare attendance

Table 1
Comparison of Hepatitis A, B and C

	Hepatitis A	Hepatitis B	Hepatitis C
Cause	Hepatitis A virus (HAV)	Hepatitis B virus (HBV)	Hepatitis C virus (HCV)
Detection	Feces of persons with HAV	Blood and certain body fluids of persons with HBV	Blood and certain body fluids of persons with HCV
Spread	Close personal contact (including sex or sharing a household); food or water contaminated with HAV	Exposure to body fluid from person infected with HBV; unprotected sex; sharing needles; needlestick; mother-infant transmission at birth	Exposure to body fluid from person infected with HCV; sharing needles; needlestick; mother-infant transmission at birth; unprotected sex (rare)
Incubation	15 to 50 days (20 average)	45 to 160 days (120 average)	14 to 180 days (45 average)
Onset	Acute	Insidious or acute	Insidious
Severity	Mild	Occasionally severe	Moderate
Risk	Household contacts or sex partners of infected persons; children in US high-rate areas during 1987-97; travelers to countries with increased rates[1]; men who have sex with men; injecting and non-injecting drug users	Sex partners of infected persons or those with multiple sex partners; men who have sex with men; injecting drug users; household contacts of chronically ill persons; infants of infected mothers; infants/children from countries with high HBV rates[2]; workers exposed to blood; chronic hemodialysis patients	Injecting drug users; clotting factor recipients before 1987; hemodialysis patients; blood and solid organ transplant recipients prior to 1992; infants of infected mothers; sex partners of infected persons or those with multiple sex partners (rare, but may increase risk of infection)
Infection	Not chronic; once infected, HAV cannot recur; 15% have prolonged illness or relapsing symptoms over 6-9 months	Chronic for 90% infected at birth, 30% infected at age 1-5 years, 2-6% infected after age 5 years; 5000 die annually in US; higher risk of liver cancer or cirrhosis	Chronic for 75-85% of those infected; chronic liver disease for 70%; 8000 to 10,000 die annually in US; higher risk of liver cancer or cirrhosis; leading indication for liver transplant
Treatment	None available; alcohol worsens prognosis	Interferon, pegylated interferon, lamivudine, adefovir, entecavir approved for chronic HBV; liver transplant; alcohol worsens prognosis; liver function testing every 6-12 months	Interferon, pegylated interferon, ribavirin; combination therapy can eliminate virus in approx. 50%; alcohol worsens prognosis; liver function testing every 6-12 months
Prevention	Hepatitis A vaccine; hand washing around food preparation, diaper changes and toilet use	Hepatitis B vaccine; safe sex; avoiding tattoos, shared needles/syringes; persons with HBV should avoid donating blood, organs, or tissues; get vaccinated against hepatitis A	No available vaccine; safe sex; avoiding tattoos, shared needles/ syringes; persons with HCV should avoid donating blood, organs or tissues; get vaccinated against hepatitis A and B

[1]Excluding Canada, Western Europe, Japan, Australia, New Zealand
[2]Including Asia, Africa, Pacific Islands, Eastern Europe, Middle East, Amazon basin

or employment, and international travel as the major risk factors for transmission of HAV.

There seems to be a predilection for hepatitis A outbreaks in late fall and early winter. The incidence of hepatitis A in developed countries has been declining in recent years, most likely as a function of improved sanitation.

Hepatitis B. HBV belongs to a family of genetically related animal viruses that are hepatotropic (i.e., have a high affinity for the liver). The highest concentrations of infectious HBV are found in blood. However, other fluids, such as semen, vaginal secretions, and saliva are also infectious. HBV can remain contagious in the environment for at least seven days. It can also be inactivated by disinfectants such as 1:10 dilutions of household bleach.

The mode of transmission may be by contact with contaminated body

secretions, percutaneously usually through accidental needlesticks or by sharing needles and/or syringes with infected persons, or by maternal-neonatal transmission. Transmission of HBV can also occur during close contact with an infected person. HBV infection via blood transfusion is now rare in the U.S. as a result of screening of blood donors. The means of transmission in 30 to 40 percent of cases remains unknown. Perinatal transmission is uncommon in the U.S.; most infections occur during delivery and are not related to breast feeding. Oral ingestion is a potential, but inefficient, route of exposure. There is a human reservoir of persistently infected persons nearly worldwide.

CDC estimates that more than 1.25 million individuals in the U.S. and 350 million people worldwide are HBV carriers. They constitute the primary reservoir of hepatitis B in humans. Approximately 90 percent of infants and 6 to 10 percent of adults in the U.S. who are infected with HBV will become carriers. Approximately 50,000 HBV cases are reported in the U.S. each year; the number of unreported cases may be 10 times greater. High rates of HBV infection occur in spouses of acutely infected persons, sexually promiscuous persons (especially men who have sex with men), health care workers exposed to blood, persons who require repeated transfusions especially with pooled blood product concentrates, residents and staff of custodial institutions for the developmentally handicapped, prisoners, and to lesser extent, family members of chronically infected patients.

Hepatitis C. Hepatitis C virus is a common chronic bloodborne infection in the U.S., accounting for an estimated 8000 to 10,000 deaths annually. Approximately four million persons in the U.S. have been infected; three million have chronic HCV infection.

Routine screening of blood donors for HBV, along with elimination of commercial blood sources in the early 1970s, reduced the frequency of transfusion-associated hepatitis. Voluntary self-exclusion of blood donors at risk for AIDS in the 1980s, along with introduction of donor screening for HIV, further reduced the probability of acquiring HCV via transfusion.

Individuals who encounter infected blood or instruments or needles, such as illicit drug users, health care workers or public safety workers, are at risk of acquiring hepatitis C infection. Other potential risks include intranasal cocaine use, tattooing and body piercing. People who live with HCV infected individuals should not share personal items such as razors, toothbrushes, and nail clippers. Women with hepatitis C infection do not need to avoid pregnancy or breast feeding. Approximately 5 percent of infants born to HCV infected females may be infected. HCV-positive mothers should abstain from breast-feeding if their nipples are cracked or bleeding.

Chronic hepatitis C appears to be a slowly progressive disease that may gradually advance over two to four decades. Newly acquired cases of hepatitis C that are diagnosed in an otherwise healthy person can often be traced back to the individual's brief period of illicit injection drug use or promiscuous sexual encounters two to four decades earlier.

Pathogenesis

The hepatitis viruses do not directly cause damage to hepatocytes; rather, the clinical manifestations and outcomes following acute hepatic damage associated with viral hepatitis are determined by the immunologic response of the host. The pathogenesis of hepatitis B has been studied to greatest extent. Persons with defective cellular immune competence are more likely to remain chronically infected rather than to clear the virus from the body.

Signs And Symptoms

Following an incubation period that varies widely according to the responsible agent (see Table 1), signs and symptoms of acute viral hepatitis appear. Prodromal symptoms of acute viral hepatitis are systemic and variable. Constitutional symptoms include anorexia, nausea, and vomiting; cough, runny nose, and sore throat; fatigue; malaise; arthralgias, myalgias, headache; and photophobia that may precede onset of jaundice by one to two weeks. Gastrointestinal symptoms are often associated with alterations in smell and taste. A low-grade fever of 100-102° F is usually more common in hepatitis A than in hepatitis B or C, except when hepatitis B occurs with the serum sickness-like syndrome. A fever of 103-104° F may accompany the symptoms, but this is rare. A dark urine and clay-colored stools one to five days before onset of clinical jaundice may be noted.

Weight loss of five to 10 pounds is common and may continue throughout the entire icteric (i.e., pertaining to jaundice) phase. The liver enlarges and may be tender, with pain and discomfort in the right upper quadrant. Ten to 20 percent of patients with acute hepatitis develop splenomegaly and cervical adenopathy.

Constitutional symptoms abate during recovery, but some liver enlargement and abnormalities in liver function tests remain. The duration of the posticteric phase may range from two to 12 weeks, and is usually more prolonged in acute hepatitis B and C. Complete recovery from hepatitis A occurs within one to two months, and in three to four months in 75 percent of persons with uncomplicated hepatitis B or C.

Prognosis

In general, hepatitis A is a self-limiting disease. Most previously healthy patients infected with HAV recover completely from their illness within weeks to six months without clinical complications. Recovery is generally complete, and followed by protection against future HAV infection. Illness may be prolonged. Relapse of clinical illness occurring

weeks to months after apparent recovery has been described. Cholestatic hepatitis, noted by protracted cholestatic jaundice with itching is another unusual variant of acute hepatitis A. Approximately 20 percent of adults with hepatitis A require hospitalization.

Ninety-five to 99 percent of otherwise healthy adults with acute HBV infection recover completely. Elderly patients and those with serious underlying medical disorders may have a prolonged recovery, and are more likely to develop severe hepatitis. The presence of ascites, peripheral edema, and hepatic encephalopathy suggest a poor prognosis. A low serum albumin and high serum bilirubin values, and hypoglycemia suggest severe hepatocellular pathology. The fatality rate in hepatitis A and B is low, but increased by old age and underlying debilitating disorders.

Hepatitis C causes signs and symptoms that are less severe than hepatitis B during the acute phase. Jaundice is less likely to occur. Fatalities are rare; the precise fatality rate is unknown. HCV ranks with alcohol as a major cause of chronic liver disease and cirrhosis in the U.S. Infection with this virus causes inflammation and low-grade damage to the liver that, over several decades, can lead to cirrhosis and hepatocellular carcinoma. HCV is the most frequent indication for liver transplantation.

Fulminant hepatitis (occurring suddenly and with great intensity) is the most feared complication of viral hepatitis. Fortunately, this massive hepatic necrosis is rare. It occurs in persons with both hepatitis B and D infections, but rare fulminant cases of hepatitis A also occur in older adults and others with underlying chronic liver disease, including chronic hepatitis B and C. More than half of all severe hepatitis cases are caused by HBV, a significant number of which are associated with HDV infection, and another portion with underlying chronic hepatitis C. Fulminant hepatitis is rare in persons with HCV alone.

A late complication of acute hepatitis B is chronic hepatitis B that occurs in a small number of patients with acute disease. Acute hepatitis is more apt to advance to chronic hepatitis when there is incomplete resolution of clinical symptoms of loss of appetite, weight loss, and fatigue and persistence of hepatomegaly; signs of multilobular (widespread) hepatic necrosis on liver biopsy during protracted, severe acute viral hepatitis; and failure of aminotransferase, bilirubin, and albumin serum levels to return to normal within six to 12 months following acute illness. Pancreatitis, myocarditis, atypical pneumonia (pulmonary virus disease with symptoms resembling those of pneumonia), aplastic anemia, and peripheral neuropathy are rare complications of viral hepatitis.

Prophylaxis

Knowledge of the natural history of hepatitis infections has steadily evolved over the past several decades. Emphasis is upon prevention through immunization of viral hepatitis since antiviral therapy is effective in only a small number of patients. Prophylaxis differs for each type of viral hepatitis.

Hepatitis A and B. The first plasma-derived HBV vaccine was licensed in the U.S. in 1982. It is no longer available in this country. A recombinant HBV vaccine was licensed in the U.S. in 1986 (Engerix-B), followed closely by another vaccine in 1989 (Recombivax HB). The first HAV vaccine was licensed in the U.S. in 1995 (Havrix), followed by approval of a second vaccine in 1996 (Vaqta). Both vaccines are inactivated whole-virus vaccines that have demonstrated safety and efficacy in preventing HAV infection. A combined HAV/HBV vaccine (Twinrix) was approved for use in the U.S. in 2001.

Hepatitis C and D. Hepatitis D infection can be prevented by vaccinating high-risk persons with hepatitis B vaccine. There is no vaccine to prevent HDV specifically. Likewise, there is no vaccine to immunize against HCV. Prevention of infection is best achieved by screening donor blood, excluding blood donors in high-risk situations, and use of highly sensitive serologic screening tests for HCV infection. There are no recommendations for babies born to mothers with hepatitis C and no restrictions for their breast feeding.

Patient Advice

It is imperative that patients who are at risk or plan to travel to areas where the viruses are found speak with their physician about preventive measures for hepatitis immunization. Vaccines for HAV and HBV are safe and effective for prophylaxis against their respective viruses.

Overview and Summary

Hepatitis is a common infection caused by one or more contagious viruses. There are safe and effective vaccines that protect against hepatitis A and B. There is no vaccine for hepatitis C or D. Individuals at risk for hepatitis should seek immunization and avoid practices and conditions that increase their susceptibility.

Continuing Education Quiz

This month's questions are taken from the article on "Acute Viral Hepatitis: Prevalence, Prognosis, and Prevention". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 10/15/08. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-06-007-H01.

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The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education for pharmacists.

1. All human hepatitis viruses are RNA viruses EXCEPT:
   a. HAV.
   b. HBV.
   c. HCV.
   d. HDV.

2. In which of the following age groups are the majority of hepatitis A infections asymptomatic?
   a. Children
   b. Adults
   c. Geriatrics

3. The Centers for Disease Control and Prevention lists all of the following as major risks for transmission of HAV EXCEPT:
   a. daycare attendance.
   b. international travel.
   c. playing with pets.
   d. sexual contact.

4. HBV belongs to a family of genetically related animal viruses that are:
   a. hepatoblastic.
   b. hepatoenteric.
   c. hepatomegalic.
   d. hepatotropic.

5. The mode of transmission of hepatitis B virus includes all of the following EXCEPT:
   a. accidental needlesticks.
   b. fecal/oral route.
   c. needle/syringe sharing by infected individuals.
   d. maternal/neonatal transmission.

6. Hepatitis viruses:
   a. directly cause damage to hepatocytes.
   b. do not directly cause damage to hepatocytes.

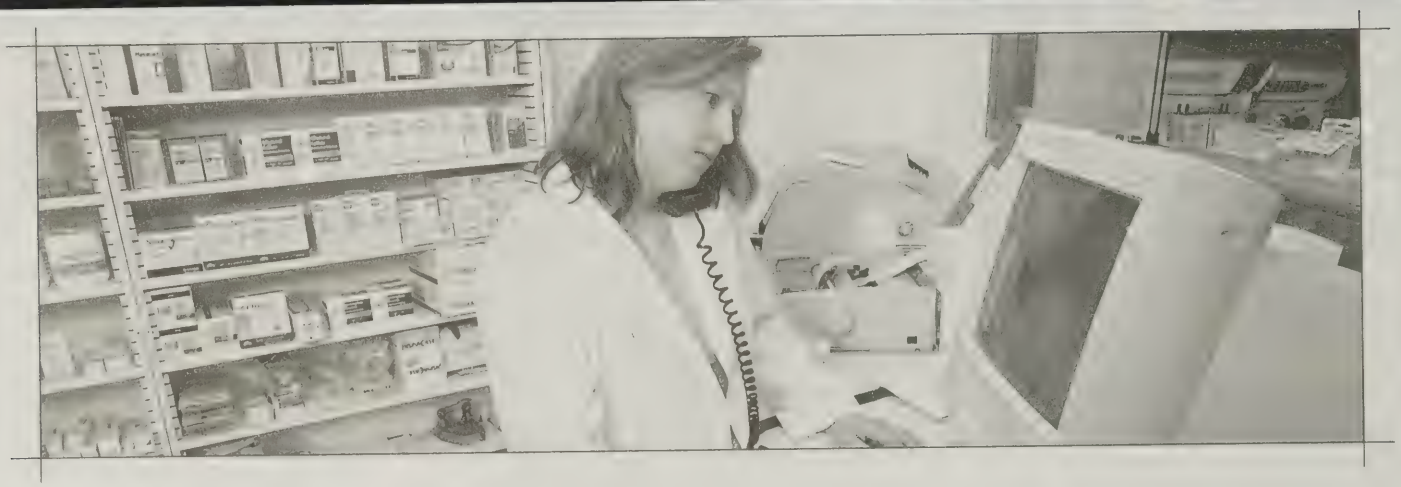
7. When comparing HAV, HBV, and HCV, which has the shortest average incubation period?
   a. HAV
   b. HBV
   c. HCV

8. Which of the following types of hepatitis viruses is most likely to cause a low-grade fever of 100-102°F?
   a. HAV
   b. HBV
   c. HCV

9. The first hepatitis virus vaccine was licensed in the U.S. in:
   a. 1952.
   b. 1962.
   c. 1972.
   d. 1982.

10. At the present time, there is no vaccine for:
   a. HAV.
   b. HBV.
   c. HCV.

Is your pharmacy running *you*?



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"MTMS is More Than MythS"

Continuing Education
"Varicella-zoster Virus Infection: the Diseases and Vaccines for Prevention"

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APRIL/MAY/JUNE 2007

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Presidents' Commentary

Virginia Apyar, President pictured in the lower level of the B. Olive Cole Pharmacy Museum

All good things must come to an end and so does my term as President of the Maryland Pharmacists Association. I am confident that our Association will continue to advance the profession of pharmacy. My confidence comes from the tremendous support I had over the past year from our membership. The transition from this president to Joe Morocco will be seamless. Joe's outstanding leadership has been evident this past year and it was greatly appreciated.

Working together with my Chairmen, the Board of Trustees and our Executive Director and staff has made my job an easy one. I have had the good fortune to have Matt Shimoda as my Chairman of the Board and Joe Morrocco as Vice-President. I had an enviable position with these 2 officers, one on my left, the other on my right. Both were dedicated, to assisting this officer. I couldn't have done it without you! Hats off to our treasurer, Walter Abel who kept us in check with our finances. A huge thank-you to my Chairman: Michelle Andoll-Comminucations, Doris Voigt-Mid-year and Convention, Brian Hose-Legislation, Professional Developement-Hoai An Truong, Membership-Mary Kremzer, and Speaker of the House-Barry Poole, and Vice-Speaker-Ruth Blatt, and ASP-Walter Fasch.

In March, the Building and Property Chairman, Doug Campbell, spent a Saturday at the Flag House being part of a program on 1812 era pharmacy and medicine. Doug was able to display some artifacts from the B. Olive Cole Museum Collection at the Star-Spangled Banner Museum. It was a great opportunity to be involved in the community and spread the word about pharmacy. Thank-you Doug, for your enthusiasm and introducing B. Olive Cole to those in attendance.

While attending the American Pharmacists Association convention in Atlanta this past March, I learned about the renovation and expansion of the headquarters building at 2215 Constitution Ave, N. W.,Washington, DC. The campaign is known as, Bringing your Medicines to Life. How fortunate that pharmacy has such a prominent address in our nation's capital! This historic national landmark is the only privately owned building on the National Mall. It was designed by John Russell Pope whose work included the National Archives, the Jefferson Memorial and DAR Constitution Hall. To support this campaign, pavers are being offered through a pledge. The pavers will be located on the East Terrace of the building. The Ohio Pharmacists Association has issued a challenge to the other state associations to make a pledge of $5,000 each to have a paver on the East Terrace. I hope the membership will be involved and Maryland will be represented. With this great symbol of pharmacy in our own backyard we have a unique opportunity to show our support. Already, many Maryland pharmacists have made a pledge for their own personal paver.

It has been an honor and a pleasure to serve as your President this past year. I am certain that our past successes combined with the efforts of the membership will build future ones. I feel very optimistic! I have had the most wonderful opportunity and I have worked with an outstanding leadership team. But, I couldn't say good-bye without recognizing the dedication and good work of Elsie, Nancy and Howard. Thank you for your support and encouragement!

All the best!

Ginger

MPhA 125th Annual Convention In Pictures
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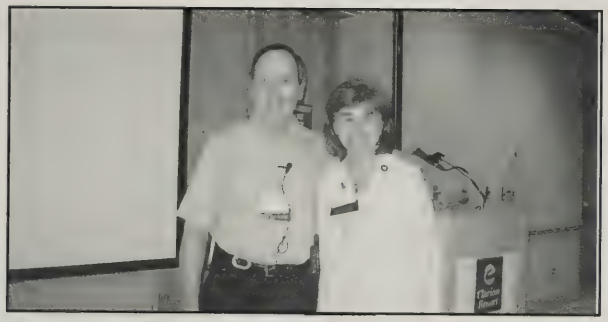

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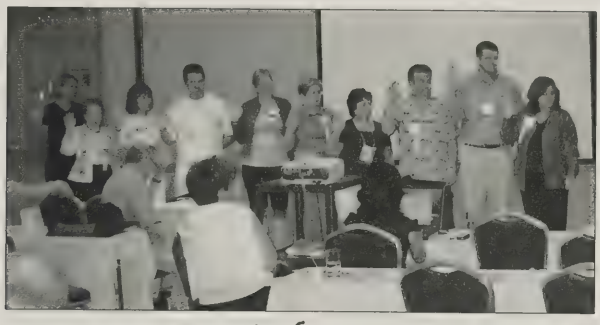

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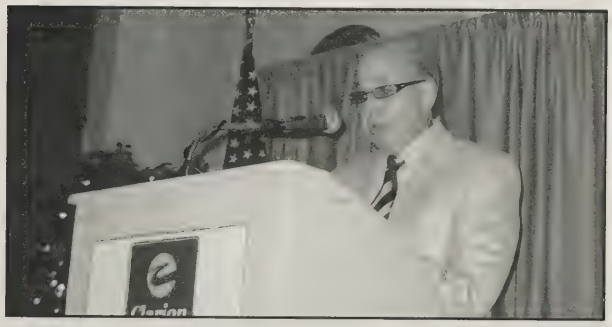

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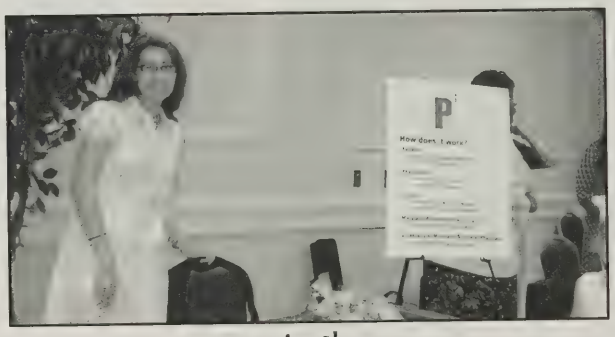

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Rx AND THE LAW

By Don McGuire, R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

NOBODY EVER READS THOSE THINGS

Steve was busy at work in his pharmacy. He was filling a prescription for one of his patient's HRT orders. Steve was very annoyed at the stack of leaflets provided with the stock bottle. He decided to simplify his life and threw the leaflets away.

Joan was at work across town in her pharmacy. Joan had ordered a motorized wheelchair for one of her patients. The chair had arrived with a multi-page instruction booklet prominently marked – "Give This Instruction Booklet to the Ultimate User". Joan decided that she could tell Mr. Jones everything that he would need to know to operate the chair and threw the booklet away.

Later that year, Steve was served with a lawsuit by Ms. Smith alleging that he didn't warn her about the dangers of HRT. Joan was also served with a lawsuit. Mr. Jones was injured when he tumbled out of the chair while maneuvering on an incline. He alleged that he was not properly instructed on the use of the chair.

When interviewed by their defense attorneys, both Steve and Joan had the same response, "Nobody ever reads those things, so I don't bother providing them." While this may be true for some patients, it is a poor risk management decision. It is a poor decision for two reasons.

First, the provision of these information leaflets may be required by law (as in the case of estrogens and other products) or by the manufacturer (as in the case of the motorized wheelchair). It can be difficult to present a credible defense to these allegations when it is clear that the information wasn't provided. Failure to follow these requirements and provide this information can be seen as a breach of duty and lead to a finding of negligence or negligence *per se*.

In legal terms, negligence is defined as the failure to use the degree of care that would have been used by a reasonable, prudent person in the same or similar circumstances. For Steve and Joan, this means measuring their actions against what a reasonable pharmacist would have done in their situations. The plaintiff-patient will prevail if they can prove that the pharmacist failed to meet the standard of care and that they were injured as a result of the pharmacist's actions.

However, in the case of negligence *per se*, the failure to follow the requirements of a statute or regulation is taken as proof of negligence. In the majority of states, the plaintiff-patient has only to prove that their injury resulted from this violation. This makes the likelihood of a plaintiff's verdict much higher.

The second reason that this kind of behavior is not good risk management is that it deprives some patients of needed information. Even if most patients won't read the booklets, the remaining patients don't even get the opportunity to read them. Think about the owner's manual for a new automobile. They can be hundreds of pages long and most people haven't read theirs from cover to cover. But, if they have a question, the manual is there for them to consult. The same thing applies to our patients. Maybe they won't go home and read it right away, but it is there to consult.

In a practical sense, it is much easier to defend a case where the patient was fully informed, but chose to ignore the information, rather than a case where the patient never received the information. We will never know which of those patients would be able to say, "I would have read it if they had given it to me." Steve or Joan's response to their defense attorneys doesn't sound very persuasive when contrasted with this statement. It is better for you and your patients to let them decide whether they will read this type of information.

© Don McGuire, R.Ph., J.D., is Assistant General Counsel at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

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A Brief History of the Pharmacists Education and Assistance Committee

Tony Tommasello, Pharmacist, Ph.D.

The Pharmacists' Education and Assistance Committee (PEAC) was created in 1983 as the "Pharmacists Rehabilitation Committee." PEAC is a 501(c)3 not-for-profit corporation with the mission to preserve professional health and public safety through advocacy and education. PEAC offers support and services to pharmacists in need of treatment and rehabilitation for alcoholism, drug abuse, chemical dependence or other physical, emotional, or mental condition. PEAC is authorized under Health Occupations 12-317 as the pharmacist rehabilitation committee for the State of Maryland.

Table 1 offers a synopsis of the PEAC lifespan in 5 year increments from its inception in 1983 to the current year. From the outset the founding members recognized that the mission of the committee was to offer assistance to ailing or impaired pharmacists and not to protect criminals. The committee had no funding, no anticipated funding stream, and no promise of state support. Among the founding members was the late Bunky Lachman who was then a member of the Board of Pharmacy. Before accepting any cases PEAC developed a treatment contract that listed the behaviors expected of pharmacists in return for the committee's advocacy and support. The contract required a thorough assessment, treatment as determined by the assessment process, strict abstinence from all mood altering chemicals, random urine monitoring, participation in a 12-step support group, cessation of pharmacy practice under certain conditions, regular contact with a PEAC monitor, and an acknowledgement that failure to adhere to the contract stipulations would result in referral of his or her case to the Board for immediate disciplinary action as warranted.

As the committee began accepting cases it became evident that pharmacists who became impaired by alcohol and especially substance abuse often ran afoul of the pharmacy practice act. Many of these cases eventually came under Board scrutiny as a result of their infractions and subsequently were sanctioned by the Board through a disciplinary action that resulted in a license suspension or revocation. Other pharmacists entered into PEAC monitored recovery completely unknown to the Board. Some of these failed to achieve stable sobriety and put the public safety at risk. Such cases were reported to the Board for immediate disciplinary action. If a pharmacist was both under a Board disciplinary order and engaged in a PEAC treatment contract PEAC provided monitoring reports to the Board's disciplinary committee through the Board's compliance officer.

As the burden of reporting grew PEAC argued that these reports had become unfunded mandates and pleaded to the Board for financial support. However, without legislation recognizing a pharmacists' rehabilitation committee no state funding could be awarded. The Board crafted legislation defining a "pharmacists' rehabilitation committee" in the law, enabling funding of its efforts, and providing liability protection for committee members when acting in good faith. Under Executive Director Rosyln Sheer the Board partnered with the School of Pharmacy and PEAC and held an art auction that raised funds to support PEAC activities while waiting for the enabling legislation to take effect.

In subsequent years the Board provided growing financial support for PEAC. The committee hired a part-time program coordinator to secure documentation from PEAC monitors, pharmacist employers, and therapists for PEAC clients. These documents formed the basis for the quarterly reports to the Board's disciplinary committee. The Board began writing language into its consent orders that required pharmacists impaired by alcohol or substance abuse to enter into a PEAC contract. The committee incorporated as a 501(c)3 not-for-profit entity in order to establish the distinction between the Board's disciplinary processes and PEAC's mission of rehabilitative intent. The balance between the Board's disciplinary authority and PEAC's offer of rehabilitative support provided the means to encourage voluntary treatment participation by substance impaired pharmacists but simultaneously ensured public safety through rapid disciplinary board action in the event of failed treatment. PEAC created ACPE approved continuing education programming in order to disseminate the message of confidential PEAC supported and directed clinical interventions for substance dependence without jeopardizing one's pharmacy career.

The Board's budget for PEAC activities grew simultaneously with the expanded mission and scope of PEAC. In an effort to promote increased referrals to PEAC of pharmacists impaired by alcohol or substance abuse the Board passed legislation requiring pharmacists to report to the Board violations of the pharmacy practice act that they observe except when those infractions are caused by alcohol or substance abuse in which case the report is to be made to the pharmacists' rehabilitation committee. This "Duty-to-Report" legislation was crafted under the leadership of Board President Stanton Ades with cooperation from PEAC.

Throughout this evolution PEAC struggled to secure funding separate from the Board. Some support was secured through contributions from MPhA and MSHP collected as voluntary additions to membership dues. Additional dollars were contributed to the Moskowitz fund established to provide financial assistance to recovering pharmacists. Although well paid, pharmacists entering substance abuse treatment are often young, married and struggling to make ends meet. The double whammy of facing expensive treatment costs and reduced income (due to a period of under- or unemployment) creates a counter therapeutic focus on income generation that sparks distraction from treatment priorities. Moskowitz funds recipients are carefully screened and support, when granted, is provided in the form of a low interest loan paid directly to creditors (mortgage holders, utility companies) and never as cash awards to individuals. Despite these contributions the vision of shared and equal funding by the pharmacy community and the Board of Pharmacy was never realized.

PEAC proposed a bold and ambitious initiative that called for a larger budget to support a part-time executive director who would energize a campaign to broadly disseminate the committee's mission to "preserve professional health and public safety through advocacy and education" and to improve the reports from PEAC to the Board's disciplinary committee. The dissemination campaign would incorporate the new "Duty-to-Report" law and emphasize the desirability of engaging in confidential assistance through PEAC before substance abuse led to serious dysfunction and Board disciplinary action. The reports were to be increased from quarterly to monthly and were to provide additional detail with respect to treatment participation. In addition, PEAC initiated site visits to recovering pharmacists at their places of employment.

PEAC's performance fell short of expectations under this initiative. PEAC met with the Board to listen to its criticism of PEAC. Subsequent to this meeting significant changes were made in PEAC staffing, the contractual arrangement was altered, and reporting to the disciplinary committee was corrected in accordance with the needs expressed by the committee members. Despite these changes the Board voted to hire a new staff member to monitor pharmacists under disciplinary action (suspension or revocation) for their compliance with the terms of the disciplinary order. Under this new arrangement PEAC continues to be the state's "pharmacist rehabilitation committee" of record as defined in HO 12-317 but is supported by the Board for only those cases that are not under a disciplinary order of the Board. This puts significant strains on the committee's financial health and creates new challenges for the committee to address in the year 2007 and beyond.

Table 1: Hallmark events in PEAC evolution

Years	Years of operation	Hallmark events
1983 – 1988	1 – 5	Creation of PEAC (originally the "Pharmacists' Rehabilitation Committee"), no funding, no paid positions
1989 – 1993	5 - 10	Board recognizes value of PEAC and helps with fundraising but provides no state support. BOP introduces enabling legislation to provide future funding, defines a "pharmacist rehabilitation committee" and provides legal protection to PEAC members and those making reports of impaired pharmacists to PEAC.
1994 – 1998	10 - 15	Board provides some funding to cover part time coordinator and some operating expenses. PEAC incorporates as a 501(c)3 not-for-profit corporation and establishes the Moskowitz fund to provide financial support for recovering pharmacists. PEAC creates ACPE approved continuing education programming on the topics of substance abuse and pharmacy practice focusing on the issue of pharmacists impaired by alcohol or substance abuse or dependence.
1999 – 2003	15 – 20	PEAC budget expands, coordinator position %FTE increases, PEAC provides quarterly reports to BOP on board referred cases. "Duty-to-Report" added to pharmacy practice act.
2004 – 2008	20 – 25	PEAC mission expands, executive director hired, breakdown between PEAC and BOP, Board votes for use of in-house staff to monitor pharmacists with substance abuse or mental health problems who are under a BOP disciplinary order. PEAC must adjust to reduced funding and the new era of relations between PEAC and BOP.

"Therapeutically Speaking... MTMS is More Than MythS"

Jennifer A. James, Pharm.D.

In partnership with MPhA and Outcomes Pharmaceutical Healthcare, LLC the author has provided training to pharmacists on the documentation and billing for Medication Therapy Management Services provided to covered beneficiaries of Medi-CareFirst. For more information about how you can participate go to www.getoutcomes.com The following article describes the process of MTMS and uses a case example to demonstrate the benefit of performing comprehensive medication reviews in detecting drug related problems related to patient adherence.

Historically, many pharmacists have offered "Brown Bag" sessions for patients to bring in their medications for review once a year, but a limited number of highly motivated patients take the initiative to participate. Of course, the prospective drug utilization review conducted as part of prescription processing has and will continue to prevent medication related problems in community pharmacies every day. However, many drug-related problems will only be detected when additional patient information is gathered. The current practice environment has expanded opportunities to use the pharmacist medication expertise with individual patients, in particular with the high risk elderly population taking multiple medications. The well known concept of pharmaceutical care has been reborn under the new banner of Medication Therapy Management Services (MTMS).

According to our eleven national pharmacy organizations "MTMS is a distinct service or group of services that optimize therapeutic outcomes for individual patients. MTMS are independent of, but can occur in conjunction with, the provision of a medication product." The core elements of MTMS in community pharmacy established by APhA and NACDS include a medication therapy review, a personal medication record, a medication action plan, intervention and referral, then documentation and follow up. The purpose of MTMS is to detect adverse events, increase appropriate medication use and create collaboration between pharmacists and prescribers. Certainly, pharmacists can also offer more complex disease state management services or participate in collaborative drug therapy management protocols for nicotine cessation, metabolic syndrome, anticoagulation or other conditions.[1]

More than three hundred Maryland community pharmacies have contracted to provide MTMS and each site may have multiple pharmacists providing services.

Both independent and corporate owners are supportive of this initiative. In order to provide MTMS, an appropriate private or semi-private area where consultations can occur is needed; a nominal investment can create one. The interpersonal skills and motivation of pharmacists to provide MTMS is likely the determining factor in success. Effective communication with the patient, caregiver and prescriber are the heart of MTMS. Additionally, written documentation is required for continuity of care as well as compensation for services.

Marketing is necessary to establish patient demand and perceived value for MTMS. Since the number of patients who have access to MTMS as a covered benefit is relatively small, targeted direct phone calls may be implemented. The following script may be used to initiate the conversation. "Hi, this is Jen, your pharmacist calling, how are you today? … I am calling to schedule an appointment to go over your medications. Your insurance will cover the cost of this service. We will sit down together and review your medications one by one to help you get the most you can from them and understand what to watch for. I will type up a list with each of your medications, directions and purpose that you can take with you. Are you interested?"

The best situation for a comprehensive medication review to occur is a private face to face encounter during a scheduled appointment time. The initial visit is usually about one hour per patient. The pharmacist collects a database including not only the medication use history, but a complete past medical history, family history, social history and focused review of systems to aid assessment of medication appropriateness. Medication related problems include interactions with conditions / drugs / foods, need for additional therapy, under or over-utilization, and adverse events. Failure to take medications due to administration technique or adherence behavior may be the easiest interventions for pharmacists to initiate directly with the patient.

Adherence is a complex and multi-factorial challenge pharmacists face daily with their patients. Access, age, cost, frequency, mental status, number of doses, knowledge, and support systems all play a role.[2] In our current busy practice environment over-utilization may most frequently be identified when adjudication fails because a refill is requested too soon. The following case was selected from practice to highlight the

interventions pharmacists can make to improve medication adherence.

The case is a 76 year old African American woman who has no specific complaint. She agreed to schedule when offered a MTMS appointment by phone and presented to the pharmacy alone, using a walker to ambulate. Her past medical history is significant for asthma, diabetes, hypertension, anxiety, resolved back pain, hip dislocation in 2000, and colon cancer in 2001. Family history includes a father with hypertension who died at 49 years old from a stroke, and a mother with diabetes who died at age 63 years of age of heart failure. Social history is negative for smoking, alcohol and illicit drugs; she lives with husband and has 3 biological and 3 adopted children. Her 12 year old daughter is keenly interested in her health, helps set up her medications and usually administers her insulin. Her medication list is: albuterol inhaler 2 puffs twice daily as needed, Azmacort 2 puffs twice daily, Humalog sliding scale < 8 units four times daily, Lantus 42 units at 9pm daily, propranolol 40mg twice daily, lisinopril 10mg daily, hydrochlorothiazide 25mg daily, fluoxetine 20mg daily, clonazepam 1mg as needed, and vitamin D 400 IU daily.

The patient reports excellent blood pressure and blood glucose control, but does not have blood glucose log or meter to review. Therefore, full assessment of medical conditions will require additional monitoring beyond the scope of her medication review visit and will not be addressed here. During the visit the patient demonstrated use of her metered dose inhaler; problems related to her technique and knowledge regarding the medications were detected. When inquiring about her actual medication use behavior, the patient described an overly complex medication schedule including dosing five times a day; breakfast, lunch, 2pm, dinner and bedtime. Both of these medication related problems were addressed during the visit.

Before leaving, the patient was provided with a neatly written list of her medications including the name, directions and purpose for use. An appointment for telephone follow up was scheduled for two weeks later. Her medication action plan in table 1 details the interventions and follow up performed. The reason, action, result coding is utilized by most documentation systems.

Table 1 – Sample Documentation of Interventions

#	Date	Reason	Action	Result	Prescriber
	Pharmacy Care Note				
1	*Visit #1*	*Complex Drug Therapy*	*Comprehensive Medication Review*	*CMR with Encounter*	*Primary Care Provider*
	Patient was contacted last week to invite for medication review appointment, presented in pharmacy today. Symptom management is priority. Patient has four chronic conditions, managed with nine prescription and one nonprescription medication. Handwritten master medication list prepared for patient.				
2	*Visit #1*	*Albuterol/Azmacort Administration / Technique*	*Patient Consultation*	*Altered Administration / Technique*	*Primary Care Provider*
	Patient knowledge deficit: patient was not shaking inhalers, actuated two puffs in the same breath. Patient did not know to use albulterol MDI prior to steroid. Patient was confused about rinsing after steroid (was rinsing after albuterol instead.) Patient accepted corrections to technique, restated and demonstrated appropriate technique.				
3	*Follow-Up Call 14 days after Visit #1*	*Propranolol Administration / Technique*	*Patient Consultation*	*Altered Administration / Technique.*	*Primary Care Provider*
	Patient believed inpatient schedule of 7 am and 2 pm dosing of propranolol was medically necessary. Suggested dosing at morning and evening meal, approximately 12 hours apart. Upon telephone follow-up two weeks later, patient had not missed any doses of propranolol, vs. previously missing 1-2 doses per week.				

After the five steps of the patient care process is complete, billing can be submitted. Pharmacists in primary care settings have billed for education and drug therapy management services under the auspices of a supervising physician for many years. Recently, pharmacist-specific CPT codes were established (Table 2). The "T" suffix indicates codes are temporary, though permanent status is sought. Similar to other CPT codes, different levels are established for new versus established patients. Uniquely, the codes are submitted in direct correlation to time spent providing care. Additionally, a place of service code (01) was approved for the pharmacy setting. In order to submit to claims a National Provider Identification (NPI) number must be obtained, applications are available online at https://nppes.cms.hhs.gov.

Table 2 - Billing Codes for Pharmacists

CPT Code	Description
0115T	New patient, first-encounter, face-to-face < 15 min
0116T	Follow up <15 min
+0117T	Add-on each 15 minutes for both new and follow up

Currently, Maryland pharmacists may participate in four Medicare Part D plans which include compensation for MTMS, or they may charge patients directly. Member Health, United Health Care, Humana and Medi-CareFirst vary widely in determining eligibility and compensation for services. Most offer MTMS only to the highest risk patients as defined by the number of medications, annual spending above $4000, and the number of chronic conditions. Plans often start by contacting the patient by mail or phone and only a select set of patients are eligible for an annual face to face visit with their community pharmacist. Medi-CareFirst is a standout in that all beneficiaries are eligible for face to face MTMS and compensation is provided on a fee for service basis. Covered services include patient counseling on new prescription, changes and selection of OTC self care items, consultations regarding drug therapy problems, cost – efficacy formulary switches and patient adherence as well as comprehensive medication reviews.

Fortunately, the practice environment is growing to include MTMS and compensation. Excellent resources from our national professional organizations establish a straightforward framework for provision of services supported by many employers. Maryland pharmacists have unique opportunities to provide care to Medicare Part D beneficiaries… Let's get started!

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Edited by Mary Lynn McPherson, Pharm.D., Professor, University of Maryland, School of Pharmacy

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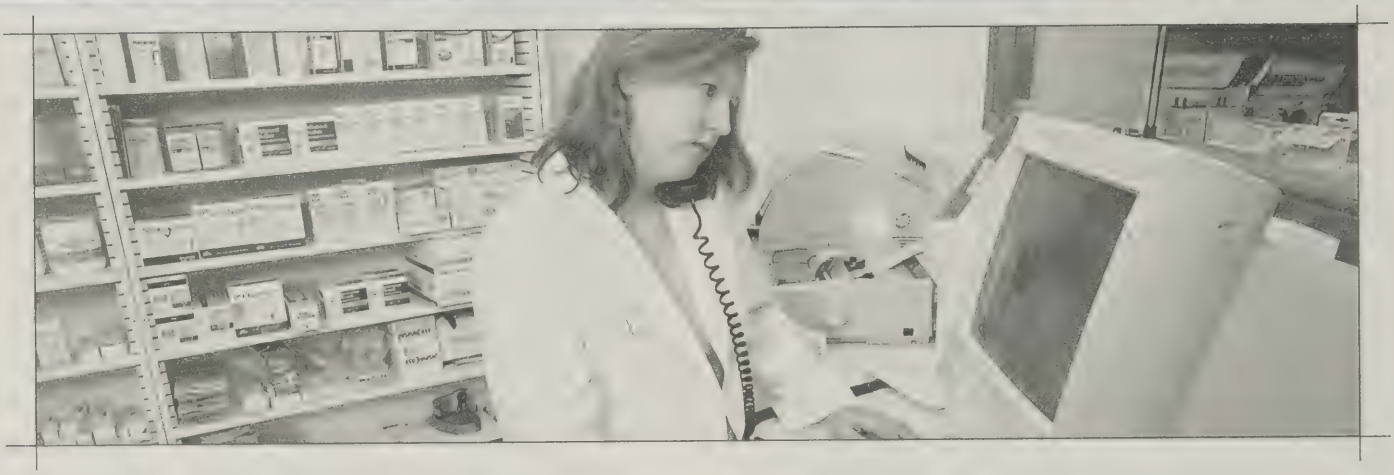

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Sexual Side Effects Associated with SSRIs

Introduction

Selective-serotonin reuptake inhibitors (SSRIs) were haled as promising treatments for depression upon their release on the market in the 1990's. They demonstrated similar efficacy compared to monoamine oxidase inhibitors (MAOIs) and the tricyclic antidepressants (TCAs), while having a much more favorable adverse effect profile.

The prominent adverse effects associated with SSRIs are GI effects, headaches, and activation or sedation (depending upon the agent). Sexual dysfunction was originally thought to be nominal among the SSRIs, especially compared to MAOIs and TCAs. Even postmarketing surveillance data of 2,487 patients taking fluoxetine demonstrated that only 0.64% of patients reported orgasmic dysfunction, and only 1.2% reported libido difficulties.[1,2] Time and further clinical study, however, elucidated a much greater incidence of sexual dysfunction among the SSRIs, ranging from 20 up to approximately 60% of patients.[3-5]

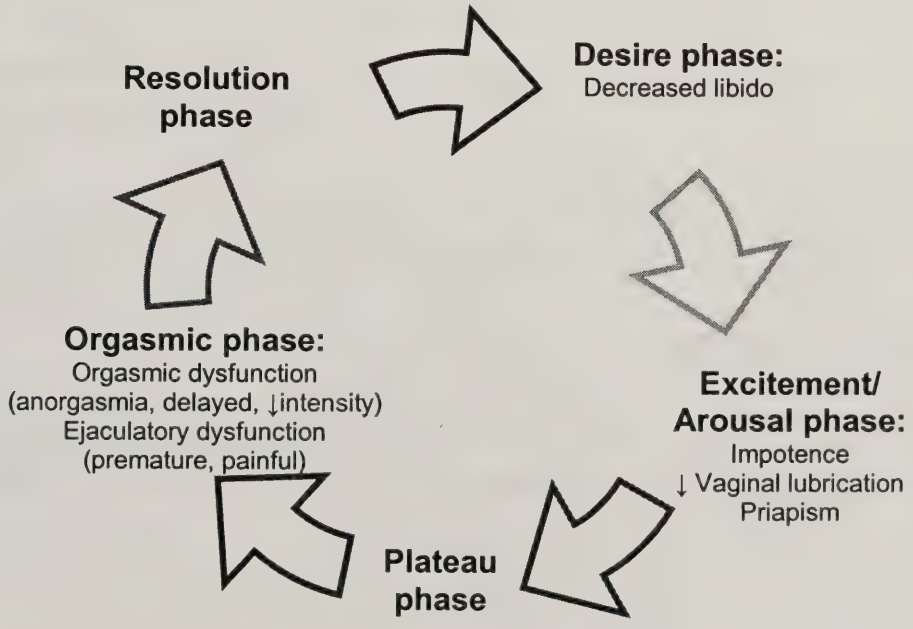
Such high incidence of sexual dysfunction is particularly concerning because it may warrant a change in therapy, or promote non-adherence. In a study of over 1,000 patients taking antidepressants, 40% of respondents who experienced sexual difficulties while on medications, stated that the dysfunction was sufficient enough to warrant discontinuation.[6] Pharmacists who are well-educated regarding antidepressant-induced sexual dysfunction are therefore poised to significantly improve patient adherence to medication and quality of life.

Sexual Side Effects Associated with SSRIs

From a treatment standpoint, it is preferable to consider medication-induced sexual effects based upon specific phases in the sexual cycle. The sexual response cycle is divided into the following phases: desire, excitement (or arousal), plateau, orgasm, and resolution.

SSRIs can have significant effects in the desire, excitement, and orgasmic phases. While dysfunction tends to be more common among men taking SSRIs, it can occur in both genders, with men typically experiencing delayed ejaculation and anorgasmia, and women experiencing decreased libido and anorgasmia. Impotence and priapism have been noted in men as well, but to a lesser extent.[7]

Figure 1. Sexual response cycle, and the SSRI-induced sexual dysfunction associated with each stage
These effects are thought to be mediated by several factors, including CNS effects (serotonin and dopamine neurotransmission, or sedative effects), hormonal effects (especially prolactin influences), and peripheral effects (alpha blockade and nitric oxide synthetase inhibition).[1,3,8-11]



The incidence of dysfunction seems to be equal overall among SSRIs, though there has been some evidence to suggest that paroxetine may be a slightly worse offender, but this has not been born out in all studies.[1,12,13]

Treatment of SSRI-Induced Sexual Dysfunction

The first step to dealing with patient complaints of sexual dysfunction is to determine whether or not the problem is medication-induced. Several other factors can affect sexual functioning, including mental illnesses (depression itself has effects on sexual functioning, as does bipolar disorder and substance abuse), psychosocial factors (stress, divorce, relational difficulties, etc.), medical conditions (cardiovascular disease, diabetes, hormonal deficiencies, and others), and medications (several medications can cause depression, and indirectly affect sexual functioning such as antihypertensives and steroids). If SSRIs are the likely cause, then practitioners must consider all available treatment options.

Copious amounts of literature exist addressing treatments for SSRI-induced sexual dysfunction, the majority of which are anecdotal case reports – though there are several clinical trials of specific treatments.

There are 5 general treatment approaches: waiting for tolerance to develop, drug holidays, dosage reduction, medication substitution, and medication augmentation (i.e., antidotes).[1,9] Table 1 summarizes the evidenced-based efficacy of these approaches.

Table 1. Efficacy of treatment strategies for SSRI-induced sexual dysfunction

	Treatment	Efficacious?	Caveats
Tolerance	N/A	Likely	- Tolerance is rare (remission in ~6%, moderate improvement in ~ 12%) after 6 months[13]
Drug Holiday	N/A	Likely	- Not effective for patients on fluoxetine[14] - May encourage non-adherence
Dosage Reduction	N/A	Possibly	- Study did not specify individual drug-dose decrease, and generalized ↓ of 50% may not be feasible in many pts[13] - May cause re-emergence of depression
Substitution	Bupropion (>300mg/d)[15,16]	Yes	
	Mirtazapine (45mg/d)[17]	Yes	
	Nefazodone (400mg/d)[18]	Yes	- Availability may be limited as brand name is no longer manufactured
Augmentation (Antidotes)	Bupropion (300mg/d)	Possibly	- Shown to have placebo effect in 2 trials with low dose (150mg/d), but efficacy in subscale of sexual desire/frequency in another[19-21] - May only be effective for problems with libido (frequency/desire) - May only be effective in women
	Sildenafil (50mg)	Yes	- May only be effective for problems with arousal - Have only shown efficacy in men[22]
	Buspirone (20-60mg/d), Amantadine (100mg), Granisetron (1-2mg), Yohimbine (various doses; 5.4-16.2mg/d))	No	- Possible efficacy as seen in case reports, but clinical trials have demonstrated a placebo effect[23-28]
	Stimulants (e.g., methylphenidate), Cyproheptadine (4-12mg)	Unlikely	- Possible efficacy as seen in case reports, but no clinical trials have reported efficacy to date[29-32]

A "watchful waiting" approach to treatment may be warranted, but is unlikely to work for most patients. The only study analyzing this effect demonstrated that more than 80% of patients had no change in sexual dysfunction after 6 months.[13]

Others have postulated a "drug holiday", where patients do not take their medication during the weekend, for example. While this method may be effective for some, it has multiple problems, not the least of which is encouraging patients to improperly adhere to medications. Espousing this method may insinuate that patients can take medications when they want to, and discontinue them at their discretion, without the aid of a healthcare professional. Also, this method has shown to be ineffective with fluoxetine due to its long half-life.[14]

Still others have reasoned that a dosage reduction may be helpful, however the study analyzing this effect offered no suggestion on individual medications, or acceptable dosage reductions (patients had their antidepressant reduced by 50% in the study). The obvious drawback to such a strategy would be a recurrence of depression, and would be particularly dangerous in patients with a history of severe depression or suicidality.

For most patients, substituting the offending agent with bupropion, mirtazapine, or nefazodone would likely be the best option, as clinical trials have demonstrated efficacy with few adverse sequelae.[15-18] Patients should be assessed on an individual basis as to which of these medications would be best, based upon comorbidities, patient and family history of response, and patient preference. Bear in mind that availability is an issue with nefazodone since the brand version (Serzone®) is no longer manufactured (in large part due to its potential for hepatotoxicity).

If it is clinically inappropriate to switch a patient from an antidepressant that has been particularly helpful, then approaching treatment from a more phase-specific standpoint would be advisable. For a patient with primarily libido complaints, a trial of bupropion might prove effective (doses of at least 300mg/d are warranted, as lower doses have shown to be ineffective).[19-21] The clinical trial supporting this treatment included mostly women, however, so the results cannot necessarily be generalized to men.[21]

For patients with arousal complaints, a trial of sildenafil (or other phosphodiesterase inhibitors) would be warranted, though clinical trials have only included men, so effects on women are uknown.[22]

Several other so-called "antidotes" have anecdotally been reported to treat SSRI-induced sexual dysfunction, including buspirone, amantadine, yohimbine, granisetron, cyproheptadine, and stimulants (a list that's not exhaustive), but these have either not been tested in clinical trials, or have been shown to have a placebo effect when tested, and should therefore be considered as last line therapy in patients receiving SSRIs.[23-32]

Counseling Tips

Choosing an appropriate therapy is only half the picture in treating sexual dysfunction, especially if the dysfunction is never assessed by a healthcare professional in the first place. Many patients never consult anyone before discontinuing their medications. Pharmacists, therefore, play a vital role in helping patients to understand the adverse sexual effects associated with SSRI's and other antidepressants, and can significantly lessen the stigma attached to such effects. With proper counseling, pharmacists can serve as liaisons to help patients maintain contact and good communication with prescribers.

As such, there are several counseling tips pharmacists ought to keep in mind regarding sexual dysfunction with SSRIs:

1. Be comfortable discussing sexuality with patients! Patients will generally mirror your confidence, or your shyness in regards to discussing sexual dysfunction.
2. Don't fear the power of suggestion! When a patient picks up an SSRI prescription for the first time, counseling them about sexual dysfunction will not *cause* them to have an adverse sexual side effect.
3. Initially, be general in your approach (i.e., say "This medication may cause changes in your sexual functioning, so be sure to let me or your physician know if that occurs so that we can properly manage these effects"). This establishes a proper rapport with the patient, and offers them an open line of communication so they are not embarrassed to discuss their concerns with you.[33]
4. Be prepared to be more specific if the patient requests more information about sexual dysfunction (i.e., say "With this type of antidepressant, men may experience difficulty achieving an erection, or orgasm (delayed ejaculation), and women may experience difficulty with sexual desire (libido) or achieving orgasm").[33]
5. Don't be afraid to ask patients about any difficulty with sexual functioning when they come in for refills. Patients may be too shy to volunteer this information. Remember that the goal is to improve adherence and quality of life, so ask!

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Darren Jay Freeman, Pharm.D.
University of Maryland School of Pharmacy
Psychiatric Pharmacy Practice Resident

Continuing Education for Pharmacists

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Varicella-zoster Virus Infection: the Diseases and Vaccines for Prevention

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., PharmD
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goals. The goals of this lesson are to discuss chickenpox and shingles, and describe the vaccines used to prevent them.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. identify the pathological responses to infection by the *Varicella zoster* virus;
2. choose key points relative to the etiology, pathogenesis, and clinical features of chickenpox and shingles;
3. recognize the vaccines for prevention of *Varicella zoster* infection in terms of their physiological and clinical characteristics; and
4. select important points to convey to patients relative to varicella infection and its prevention.

Gossel

Wuest

Introduction

Varicella zoster virus (VZV) causes two distinct clinical entities: varicella (chickenpox) and herpes zoster (shingles). Chickenpox is a widespread and extremely contagious infection of childhood. Latent VZV may reactivate later as shingles.

Etiology, Pathogenesis and Pathology

The association between chickenpox and shingles has been known for nearly 100 years. Viral isolates obtained from patients with chickenpox and shingles produce similar changes in tissue culture, suggesting that the viruses are biologically similar. VZV is a member of the family *Herpesviridae*.

Primary Infection. VZV enters the host via the respiratory route and conjunctiva. The virus is believed to replicate within the nasopharynx and regional lymph nodes, which results in infiltration of the reticuloendothelial system with eventual appearance in the blood and development of primary viremia. The virus is then disseminated to other tissues including the liver, spleen, and sensory ganglia. Further replication occurs in the viscera, followed by viral infection of the skin. Viremia in patients with chickenpox manifests as diffuse and scattered lesions involving the dermis and epidermis. The vesicles, which contain infectious virus, ultimately rupture and release fluid, or will be reabsorbed slowly.

Recurrent Infection. Once the primary (initial) outbreak has subsided, the virus presumably retreats into the dorsal root ganglia where it can remain dormant for years until some excitatory factor reactivates it. The mechanism of reactivation that results in herpes zoster remains unknown. Examination of representative dorsal root ganglia during active herpes zoster reveals hemorrhage, edema, and lymphocytic infiltration.

In the immunocompetent host, active replication of VZV in other organs, such as the lung or brain, can occur during either chickenpox or herpes zoster, but is uncommon. Pulmonary involvement is characterized by interstitial pneumonitis and pulmonary hemorrhage. Central nervous system involvement results in histopathologic changes in the brain similar to those encountered in measles and other virus-induced inflammatory responses. Hemorrhagic necrosis of the brain, as is typical with herpes simplex virus encephalitis, is uncommon in VZV infection.

Epidemiology and Clinical Manifestations

Chickenpox. Humans are the only host for VZV. With an attack rate of 90 percent or more of susceptible individuals, chickenpox is highly contagious. Males and females of all races are infected equally. Normally endemic in the population at large, the virus becomes epidemic in susceptible individuals during seasonal peaks (late winter and early spring in

temperate climates). In the U.S., the incidence is highest between March and May, and lowest between September and November. Children between ages five and nine years are most commonly affected, and account for half of all infections. The majority of other cases involve young people one to four years and 10 to 14 years of age. Since introduction of the varicella vaccine for children, varicella cases have been reduced by 90 percent.

The incubation period for varicella ranges from 10 to 21 days; the usual period is 14 to 16 days. Secondary attack rates between 70 and 90 percent are reported in susceptible siblings within a household. Infected persons remain infectious for approximately 48 hours prior to onset of the vesicular rash, throughout the period of vesicle formation (usually four to five days), and until all vesicles become crusted. Once all skin lesions have crusted, an individual no longer transmits VZV. Indirect transmission via an immunized third person is not believed to occur.

The patient with chickenpox may have a mild prodrome (warning signs) of low-grade fever and malaise occurring one to two days before onset of rash. Oftentimes in children, the rash is the first sign of disease. Immunocompetent patients usually develop a benign illness that is associated with weakness and exhaustion, and temperatures of 100^{0} to 103^{0} F that last three to five days. Skin lesions, which are the hallmark of infection, usually appear first on the face and scalp, then on the trunk, and then on the extremities. The rash is generalized and causes itching. It progresses rapidly from discolored spots of skin that are not elevated (macules) to small circumscribed, solid elevations of skin (papules) to vesicular lesions before crusting. A typical case includes each form of lesion and scabs, all in various stages of progression. Most lesions are small (5 to 10 mm), have a red base, and appear over two to four days. Lesions can also appear on the mucous membranes of the oropharynx, respiratory tract, vagina, conjunctiva, and cornea. Healthy children usually have 200 to 500 lesions. Recovery by an immunocompetent person usually results in lifetime immunity from another attack of chickenpox. A repeat infection of chickenpox may occur in immunocompromised persons. As is also true of other viral infections, re-exposure to natural varicella may lead to reinfection that, fortunately, boosts the person's antibody titres without causing clinical illness.

Complications of Chickenpox. Secondary bacterial infection of skin lesions can follow, usually caused by *Streptococcus pyogenes* or *Staphylococcus aureus*, and is the most common infectious complication of varicella. Secondary infection is the most frequent cause of hospitalization and outpatient medical visits. Viral shedding from skin lesions after scratching may result in infection. Varicella pneumonia is the most serious complication in chickenpox, appearing more often in adults (up to 20 percent of all cases) than in children. The complication usually begins three to five days into the illness. Patients experience rapid respirations (tachypnea), cough, dyspnea, and fever most frequently; and cyanosis, pleuritic chest pain, and expectoration of blood or blood-stained sputum (hemoptysis) less frequently. Pneumonia following chicken pox is usually viral but may be bacterial. Secondary bacterial pneumonia is more likely to occur in children under the age of one, rather than in older children. About 12,000 people are hospitalized with chickenpox each year in the U.S., with about 100 deaths reported.

Herpes Zoster. Herpes zoster is more commonly called shingles, from the Latin *cingulum*, meaning "girdle." Similarly, the descriptor *zoster* is derived from the classical Greek, referring to a "belt-like binding" (i.e., a zoster) used by warriors to secure their armor.

Herpes zoster is a sporadic disease. It is the reactivated form of the VZV from the dorsal root ganglia; most patients who develop shingles have not had a recent exposure to another individual with VZV infection. It is estimated that 500,000 to 1 million people in the U.S. experience an outbreak of shingles each year. A recently released FDA report stated that shingles is estimated to affect two in every 10 people in their lifetime. Unlike chickenpox, shingles occurs throughout the year. Herpes zoster is contagious to those who have not had varicella, or have not received the varicella vaccine. Individuals can contract chickenpox from close contact with a person who has shingles. However, a person cannot catch shingles from someone else.

More than 90 percent of patients with shingles have serological evidence of a previous VZV infection. It is not possible to predict who will develop the condition or what triggers its reactivation. It may occur at any age, but its incidence is greatest during the sixth decade of life and beyond, and in those with a compromised immune system.

The classic presentation of shingles begins as a prodrome of fever, tiredness, and headaches that may precede eruption of vesicles by several days. Lesions are usually localized to a single dermatome (the area of skin supplied with afferent nerve fibers by a single posterior spinal root). Mild-to-moderate burning or tingling occurs within the affected dermatome. Dermatomes from T3 to L3 are most commonly involved and often associated with severe pain that may be misdiagnosed as myocardial infarction or renal colic. Zoster ophthalmicus is a form of herpes zoster involving the ophthalmic ganglion of the trigeminal nerve. It results in painful eye inflammation with impaired vision. Without treatment, it can lead to blindness. Zoster ophthalmicus accounts for approximately 10 to 25 percent of herpes zoster cases.

As stated earlier, the factors that lead to the reactivation of VZV are not well understood. Known

physiologic factors include increasing age, immunosuppression, intrauterine exposure to varicella, and outbreak of varicella at younger than 18 months of age. Reactivation is usually benign in children. Often preceding the appearance of lesions by 48 to 72 hours, a red maculopapular (lesions with a flat base surrounding a solid elevation in the center) rash forms unilaterally along the dermatome, and changes rapidly into vesicular lesions reminiscent of the original chickenpox outbreak. Lesions may cover more than one dermatome and occasionally cross the midline to the other side of the body. They may remain few in number and continue to form for up to three to five days. The lesions usually begin to dry and scab three to five days after appearance. The vesicular fluid becomes cloudy with pus. The duration of illness generally lasts seven to 10 days, but it may take two to four weeks before the skin returns to normal. The rash may leave scarring and changes in pigmentation. Seronegative individuals (persons without antibodies to an earlier varicella infection) may become infected with chickenpox. On rare occasion, pain localized to a dermatome will be felt in the absence of skin lesions. When branches of the trigeminal nerve are involved, lesions may appear on the face, in the eyes, or in the mouth or on the tongue.

Herpes Zoster Complications. Pain associated with acute neuritis that leads to development of postherpetic neuralgia (PHN) is the most debilitating complication of herpes zoster, in both the normal and immunocompromised host. PHN is a condition where pain accompanying the rash persists long after the lesions have disappeared, commonly more than 30 days after the lesions have healed. It is best characterized as unrelenting sharp, burning, and stabbing pain that makes daily activities such as dressing and bathing almost unbearable. PHN is rare in young patients. At least half of patients over age 50 with shingles report pain of some extent months after the cutaneous manifestations have resolved. Altered sensation in the dermatome, resulting in abnormally reduced or greater sensitivity to touch is common. Other complications include inflammation of the brain or spinal cord, and paralysis of peripheral nerves.

Symptoms of shingles will be more severe in the immunocompromised host. Lesions continue to appear for over a week, and scab formation is usually incomplete until three weeks into the illness. Cutaneous dissemination develops in approximately 40 percent of patients with Hodgkin's disease and non-Hodgkin's lymphoma. In these patients, the risk of pneumonitis, meningoencephalitis, hepatitis, and other serious complications increase. Even in immunocompromised patients, however, disseminated zoster is rarely fatal.

Prevention

Chickenpox. Varicella vaccine (Varivax) is a live, attenuated viral vaccine (Table 1). Isolated in the early 1970s from vesicular fluid obtained from an otherwise healthy child with varicella disease, varicella vaccine was licensed in the U.S. in 1995.

The vaccine is estimated to be 70 to 90 percent effective against infection, and 85 to 95 percent effective against moderate or severe disease. More than 90 percent of vaccine responders will maintain antibody levels for at least six years. Among healthy adolescents and adults, 78 percent of vaccine recipients develop antibodies after one dose, with 99 percent developing them after a second dose administered four to eight weeks later.

Immunity appears to be long-lasting and is probably permanent in the majority of recipients. Breakthrough infection (i.e., varicella disease in a vaccinated person) will be significantly milder, with fewer lesions, many of which will be maculopapular rather than vesicular; most patients will not have fever.

Most clinical investigations have not identified time since vaccination as a risk factor for breakthrough varicella. The presence of asthma, use of steroids, and younger age (i.e., younger than 15 months) have been suggested as being risk factors for breakthrough varicella.

Varivax is recommended for all children without contraindications at 12 to 18 months of age. It may be given regardless of prior history of varicella; however, vaccination is not necessary for children with a reliable history of chickenpox. The vaccine is also recommended for all children without evidence of varicella immunity by their thirteenth birthday. Children who have not been vaccinated previously and who do not have a reliable history of chickenpox are considered to be susceptible for chickenpox. Efforts should be made to ensure varicella immunity by this age, because varicella disease is more severe, complications more frequent, and two doses of vaccine are required

Table 1
Comparison of Vaccines

Vaccine	Contents	Use	Administration
Varicella (Varivax)*	Live, attenuated vaccine	Vaccination against *chickenpox* in persons 12 months of age & older	12 mo-12 yr: 0.5 ml sc; >13 yr: 0.5 mL sc with second dose 4-8 weeks later
Zoster (Zostavax)*	Live, attenuated varicella-zoster virus	Prevention of *shingles* in persons 60 years of age and older	>60 yr: single dose administered sc

*For more information visit: www.Varivax.com or www.Zostavax.com

Table 2
Patient Advice for the Zoster Vaccine

- This vaccine is to be used for adults 60 years of age and older to prevent shingles (also known as zoster). Only your healthcare provider can decide if the vaccine is right for you.
- This vaccine works by helping your immune system protect you from getting shingles and the pain and other complications that come with shingles. If you do get shingles even though you have been vaccinated, the vaccine may help prevent the severe nerve pain that can follow shingles.
- As with any vaccine, this one may not protect everyone who receives it.
- This vaccine should not be used to treat shingles once you have it. If you do get shingles, contact your healthcare provider within the first few days of getting the rash.
- You should not receive the vaccine if you: 1) are allergic to any of its ingredients, including allergies to gelatin or neomycin; 2) have a weakened immune system; 3) have active tuberculosis that is not being treated; or 4) are pregnant or may be pregnant.
- Be sure to tell your healthcare provider before receiving the vaccine if you: 1) have or have had any medical problems; 2) are taking any medications, including those that might weaken your immune system; 3) are breastfeeding; 4) have had shingles in the past; or 5) may be in close contact with someone who may be pregnant and has not had chickenpox or been vaccinated against chickenpox, or someone who has problems with their immune system.
- Contact your healthcare provider right away if any medical condition you have gets worse or you develop any new or unusual symptoms after you receive this vaccine.

after 13 years of age. The Advisory Committee on Immunization Practices has provisionally recommended two doses for individuals under 13 years of age. This change in vaccine schedule is expected to be adopted in January of 2007. (http://www.cdc.gov/nip/publications/aciplist.htm)

The vaccine should be administered subcutaneously in the deltoid muscle. It is safe and effective in children when administered concomitantly with measles-mumps-rubella (MMR) vaccine at different sites with separate syringes. A combined live attenuated measles-mumps-rubella-varicella (MMRV) vaccine (ProQuad®) is licensed for persons 12 months to 12 years of age.

Shingles. Zostavax is a recently licensed (May 2006) product that reduces the risk of acquiring shingles in persons 60 years of age and older (Table 1). It is the only vaccine licensed in the U.S. that reduces the risk of reactivation of the varicella zoster virus. It should not be used to treat established shingles. The vaccine is not a substitute for varicella virus vaccine, and should not be used to immunize children against chickenpox. Likewise, Varivax is not a substitute for Zostavax. Potency of Varivax is considerably lower than that of Zostavax. The higher dose of the zoster vaccine seems to be necessary to overcome the immunosenescence (i.e., reduced response of the immune system) associated with aging. For this reason, the vaccine intended to protect against chickenpox is not to be used for shingles prevention in adults.

Prevention of shingles with the zoster vaccine should eventually result in fewer cases of shingles along with the multiple health benefits that will follow. A double-blind, placebo-controlled pre-marketing study of the vaccine was conducted in approximately 38,000 individuals. Overall, the vaccine reduced the occurrence of shingles by 64 percent in persons aged 60 to 69 years. Effectiveness declined with increasing age: 41 percent for the 70 to 79 age group; 18 percent for those 80 years of age and older. Additionally, duration of pain following onset of shingles was reduced slightly in those who developed shingles despite being vaccinated. Specifically, pain in the vaccine group lasted an average of 20 days, versus 22 days in the placebo group. Pain severity did not differ among the two groups.

In this study, serious adverse events in persons receiving the vaccine were noted in 1.9 percent of recipients, verses 1.3 percent of persons who received placebo. The number of deaths in both groups was equal. FDA concluded that the study results were inconclusive; the manufacturer continues to investigate safety.

The most common adverse reactions in persons who received the vaccine included redness, pain, itching, tenderness, and swelling at the injection site. Headache was also reported.

Zostavax should be administered subcutaneously in the upper arm (deltoid muscle). The entire contents of a vial should be given. Advice to convey to persons vaccinated with Zostavax or their caregivers is provided in Table 2.

Overview and Summary

Chickenpox and shingles are both caused by *Varicella zoster*. Whereas chickenpox results from acute infection, shingles follows when the dormant virus is reactivated. Vaccination of individuals >12 months of age with the varicella vaccine effectively prevents chickenpox; vaccination of adults >60 years with the zoster vaccine may prevent shingles outbreaks. The two vaccines are not interchangeable and should only be used for their approved indication.

Continuing Education Quiz

This month's questions are taken from the article on "Varicella-zoster Virus Infection: the Diseases and Vaccines for Prevention". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 12/15/09. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-06-012-H01.

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The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education for pharmacists.

1. Once the primary outbreak of *Varicella zoster* infection has subsided, the virus presumably retreats to the:
   a. posterior root ganglia.
   b. anterior root ganglia.
   c. proximal root ganglia.
   d. dorsal root ganglia.

2. Central nervous system involvement in a VZV infection results in histopathologic changes similar to:
   a. measles.
   b. smallpox.
   c. mumps.
   d. influenza.

3. In the U.S., the incidence of chickenpox is highest from:
   a. December to February.
   b. March to May.
   c. June to August.
   d. September to November.

4. For varicella, persons remain infectious from how long prior to onset of the vesicular rash until the time all vesicles have crusted?
   a. 12 hours
   b. 24 hours
   c. 48 hours
   d. 96 hours

5. Secondary bacterial infections of chickenpox lesions are usually caused by:
   a. *E. coli.*
   b. *H. influenzae.*
   c. *P. aeruginosa.*
   d. *S. aureus.*

6. Which of the following statements is FALSE?
   a. Shingles mainly occur March to May.
   b. Herpes zoster is a common name for shingles.
   c. Shingles is more prevalent after age 60.
   d. A person cannot catch shingles from someone else.

7. A lesion with a flat base surrounding a solid elevation in the center can be described as:
   a. dermatomal.
   b. maculopapular.
   c. pustular.
   d. vesicular.

8. The most debilitating complication of Herpes zoster is:
   a. arthralgia.
   b. myalgia.
   c. neuralgia.

9. When Varivax is given to a patient older than 13 years of age, the number of doses required is (are):
   a. one.
   b. two.
   c. three.
   d. four.

10. Varivax and Zostavax are:
   a. not interchangeable.
   b. interchangeable.

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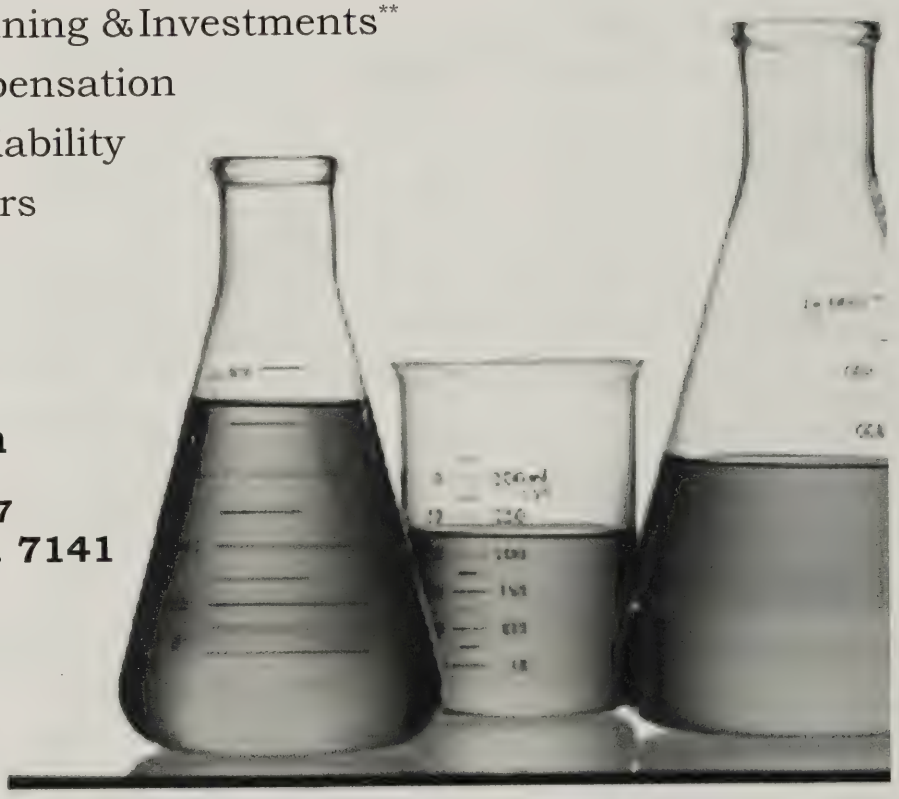

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Joseph Marrocco, P.D.

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MARYLAND PHARMACISTS ASSOCIATION JULY/AUG./SEPT. 2007

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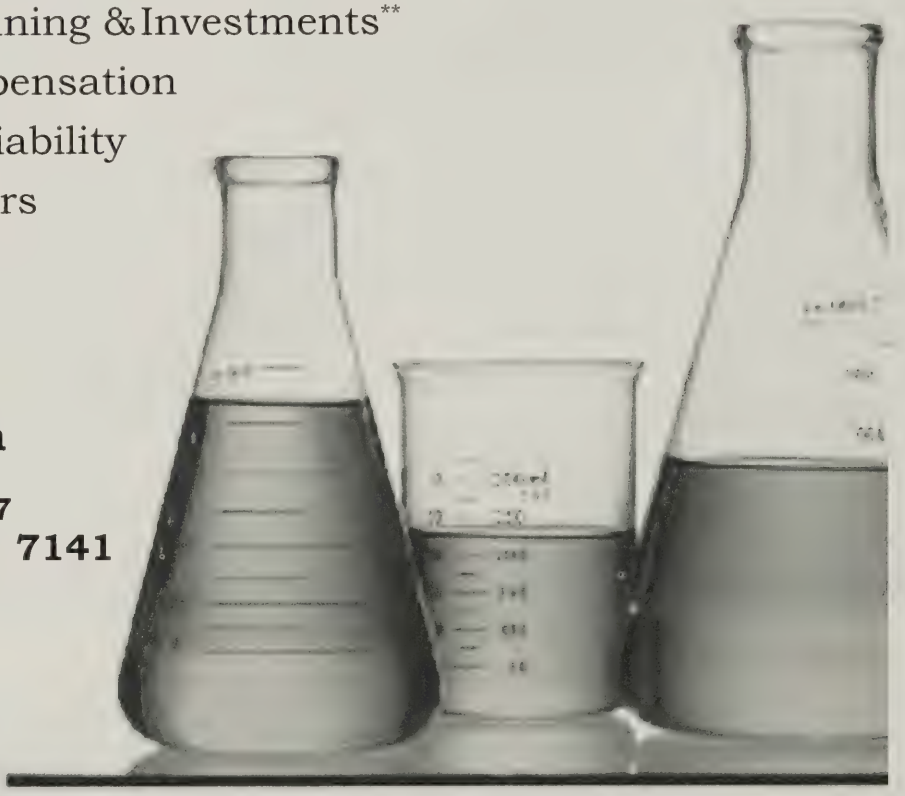

Dave Geoghegan
P.O. Box 177
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Presidents' Statement

Joseph Marrocco, P.D.
President

During a recently televised interview on the CBS "60 Minutes" news program, U.S. Comptroller General, David Walker, warned that the new Medicare Plan D prescription drug program is so "financially irresponsible" that it could plunge the entire Medicare program into bankruptcy. Walker said that, when the first wave of baby boomers start receiving Medicare benefits in 3 years, the result will be a "tsunami of spending that could swamp our ship of state if we don't get serious" about controlling health care and entitlement program costs.
Walker, the nation's top accountant and head of the Government Accountability Office, characterized the new prescription drug benefit as the final straw for an already fiscally shaky Medicare program.

It is my desire to encourage and engage our pharmacy colleagues in all facets of practice to focus on the way medications are used, rather than what they cost us to buy. Today's financial incentives are short term, i.e. generic usage. A shift with the P3 Project and E-prescribing communications, medication problems and drug misadventures can be prevented thus allowing pharmacists to rely more on these services and less on dwindling prescription reimbursements.

The emerging medication therapy management programs serve as an avenue for payors to develop incentives that reward pharmacies for assuming a critical advisory role in the health care system. Pharmacists must be able to communicate with prescribers via the e-prescribing system and allow information re insurance benefits, eligibility, and formulary. Information on patient medication histories, data on drug interactions, cost comparisons, and therapeutic alternatives to a medication prescribed are vital. To service the patient now and not a couple days later, the system must allow for the ability to transmit and process prior-authorization requests, and the cancellation of—or changes to—any prescription already transmitted.

MPhA strongly supports pharmacists who show a willingness to participate in these programs, and in so doing will ensure a future that is both more secure and even more valuable to others.

To accomplish these goals, I invite all of our pharmacist colleagues to become member of our state association, and an ACTIVE one at that. MPhA is a team of equals—there is no "pecking" order. There are no try-outs, no cuts, everyone makes the varsity squad. While growing up, my dad would advise me that the good Lord created us with two eyes, two ears, but just one mouth for a reason. I assure you that MPhA will continue to be a pro-active, not merely reactive association. I encourage your participation, in any matter or means you feel an interest, desire, or passion. "Doc" Fred Abramson always advises his students to surround yourself with SMART people—and I know there are a lot of you out there.

Dr. George Voxakis, who is one of our Maryland pharmacy icons, spoke at a pharmacy dinner meeting and remarked, two of the best choices in life one can make are the field of study and career path we choose, and who we partner with. Dean David Knapp, Professors Magaly Rodriguez de Bittner, Cynthia Boyle, Robert Beardsley, et al, continually raise the bar for our pharmacy profession and always keep us in the loop re pharmacy knowledge, trends, research and development. Howard, Cynthia, Matt, and Ginger, you have taken MPhA to new and higher heights and expectations…I pledge to ALL PHARMACISTS to continue this charted course—with our fellow colleagues and profession in mind—you deserve our TRUST.

The Centers for Medicare & Medicaid Services (CMS) requires network pharmacies to post the "Medicare Prescription Drug Coverage and Your Rights" notice within the pharmacy, or to distribute it to patients. This notice advises Medicare beneficiaries of their rights to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist.

Additionally, CMS requires long-term-care (LTC) pharmacies on and off-site to send this notice to the location in the LTC facility designated to accept such notices.

Please post this notice in a location that is easily seen by your patients.

Medicare Prescription Drug Coverage and Your Rights

You **have the right to get a written explanation** from your Medicare drug plan if:

- Your doctor or pharmacist tells you that your Medicare drug plan will not cover a prescription drug in the amount or form prescribed by your doctor.
- You are asked to pay a different cost-sharing amount than you think you are required to pay for a prescription drug.

The Medicare drug plan's written explanation will give you the specific reasons why the prescription drug is not covered and will explain how to request an appeal if you disagree with the drug plan's decision.

You **have the right to ask** your Medicare drug plan **for an exception** if:

- You believe you need a drug that is not on your drug plan's list of covered drugs. The list of covered drugs is called a "formulary;" or
- You believe you should get a drug you need at a lower cost-sharing amount.

What you need to do:

- Contact your Medicare drug plan to ask for a written explanation about why a prescription is not covered or to ask for an exception if you believe you need a drug that is not on your drug plan's formulary or believe you should get a drug you need at a lower cost-sharing amount.
- Refer to the benefits booklet you received from your Medicare drug plan or call 1-800-MEDICARE to find out how to contact your drug plan.
- When you contact your Medicare drug plan, be ready to tell them:

1. The prescription drug(s) that you believe you need.
2. The name of the pharmacy or physician who told you that the prescription drug(s) is not covered.
3. The date you were told that the prescription drug(s) is not covered.

The Interdisciplinary Experience : A Student Pharmacist's Perspective

By Velma U. Nwosu, PharmD Candidate

As a fourth year student I find myself in reflection. Of all the academic experience that I have accumulated whilst attending the University of Maryland, School of Pharmacy, most resonant in my mind are my interdisciplinary pursuits. Among them are those in the areas of palliative care, geriatrics, psychiatry, and childhood obesity. This analysis underscores the value and essential nature of an interdisciplinary pharmacy education. My objective is to charge students of pharmacy and other professions with the task of more frequent involvement in interdisciplinary learning opportunities.

What is interdisciplinary learning?
Understanding the interdisciplinary team revolves around the premise that we, as health professionals, are enlisted to assist those in our community. To this end, we have also been enlisted as community learners, gathering professional knowledge from one another. The procurement of such knowledge is facilitated via communication, collaboration, and cooperation, three of the most important tenants of effective interdisciplinary relationships.

The structure of interdisciplinary working relationships consists of disciplines or team members from various areas of expertise, but each discipline learns together, tackling topics that are usually problem-based and/ or patient-based. Comprehensive patient care is paramount and the common goal in the interdisciplinary healthcare setting is the creation of feasible or useful outcomes.[1] Integration of patient-specific needs and simultaneous instruction, make the interdisciplinary experience unique. An interdisciplinary learning experience combines therapeutic instruction with social and professional interactions amongst participants. There are some areas that are inherently interdisciplinary, such as gerontology, while there are others that do not lend themselves to this type of practice model.

Many often interchange interdisciplinary practice with multidisciplinary endeavors. The reality is these two terms are at odds not merely in their execution but also in the manner with which providers communicate when engaged in either multidisciplinary versus interdisciplinary groups. In the multidisciplinary team, members usually work in parallel, drawing information from one another but do not have a common understanding of issues that could influence interventions, while interdisciplinary groups utilize more inclusive language and share information between team members. [2]

Why contribute to interdisciplinary learning?
There has been a considerable paradigm shift from a product-centered focus towards a patient-centered focus in pharmacy.[3] The Accreditation Council for Pharmacy Education (ACPE) Standards have since newly approved guidelines, effective in 2007, which mandate that pharmacy graduates should be able to provide pharmaceutical care in cooperation with patients, prescribers, and other members of an inter-professional health care team, to promote health improvement, wellness, and disease prevention.[4] The Institute of Medicine (IOM) stipulates that proficiency while working as part of an interdisciplinary team is one of the five core attributes that students and practicing health professionals should possess.[5] Given this paradigm shift in pharmacy, interdisciplinary collaborative opportunities are the best way to actively link or integrate students' education with future clinical practice.

Aside from driving educational expectations, patient-centered pharmacy practice has been underscored by the provision of population-based healthcare. Interdisciplinary teams are a means of enhancing access to healthcare in rural and urban underserved populations in the United States. Unlike medical students and nurses, pharmacy students can still graduate from colleges of pharmacy with hardly any patient contact throughout their studies.[3] It is important that we look toward our peers in medicine, nursing, allied healthcare, and social work to supplement our knowledge of patient populations as we select appropriately indicated, effective, safe, and convenient drug therapy. Collaborative teams have proven to be a successful model for the management of a host of chronic illnesses, including but not limited to, diabetes[6] and chronic kidney disease[7].

Pharmacists, working in tandem with primary care providers, aid in the prevention of secondary consequences and the promotion of therapy maintenance, through discharge planning and medication-therapy management.

Conclusions

Interdisciplinary course offerings, at the University of Maryland, School of Pharmacy have been the most enjoyable and fully integrative experiences, combining pharmacy training and interprofessional communication skills. Overall, these opportunities have bestowed me with a sense of educational satisfaction and a feeling of confidence. In fact, true understanding of clinical pharmacy and therapeutics did not come about until I was exposed to an interdisciplinary team.

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Rx AND THE LAW

By Kyle J. Starostka
And Don R. McGuire Jr., R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

NATIONAL PRACTITIONER DATA BANK

Malpractice claims are brought against practitioners more often than wanted in the health care system. Although many malpractice claims arise from legitimate negligence, there are also frivolous lawsuits that are pursued by over-litigious parties that cloud the system. The real concern is protecting patients from practitioners that are truly being negligent. Congress became aware of problems arising nationwide from the increasing occurrence of medical malpractice claims and the NPDB was one solution to these problems.

While pharmacists may not be aware of the NPDB, they are included in the system. The NPDB is a system that provides a vast amount of information that is helpful in evaluating the performance of pharmacists, doctors, dentists, and other health care professionals. The database was enacted under the Health Care Quality Improvement Act of 1986 in response to increasing criticism about the failure of medical licensing authorities to protect patients from negligent health practitioners, including pharmacists. The NPDB was established to ensure that unprofessional or incompetent health care practitioners are not able to move from state to state and compromise the quality of health care.

The NPDB obtains submitted information from state licensing boards, hospitals, professional societies, medical malpractice payers (for example, insurance carriers), the U.S. Drug Enforcement Administration, and other health care entities. These organizations submit information pertaining to payments made to satisfy medical malpractice claims and adverse actions taken against practitioners with respect to their professional competence or conduct. Medical malpractice payments that do not identify individual practitioners are not to be reported to the NPDB. For example, if a payment is made solely for an entity (i.e. hospital, clinic, or pharmacy) and does not identify an individual practitioner, it can not be reported to the NPDB. The Health Care Quality Improvement Act requires health care entities to report adverse actions to the data bank which concern suspension, curtailment, or revocation of a practitioner's clinical privileges and similarly requires that state licensing boards report any licensure revocation, suspension, or reprimand to a health care practitioner's license. Hospitals, professional societies, and state licensing boards have access to information available in the NPDB and can query the data bank to help assist in conducting investigations of the qualifications

of the health care practitioner to whom they seek to license, hire, or grant clinical privileges. Health care practitioners may do a self-query on themselves at any time for a set fee. Plaintiffs representing themselves or plaintiff's attorneys may query the data bank only under certain circumstances. As of now, the NPDB is not a consumer education tool and does not allow the general public to access information.

The data bank processes information exactly how it is filed, so reporting entities are responsible for the accuracy of the information that they submit and changes to a report may be submitted only by reporting entities. Subject(s) involved in a report will be notified by mail after the NPDB is finished processing information. Subjects that receive a notification letter should thoroughly review the report for accuracy. If inaccurate information is found, the subject involved must contact the reporting entity and request a correction to the report. If the reporting entity declines to change the report and the disagreement cannot be resolved between the subject and reporting entity, the subject must go through the NPDB to add a personal statement to the report or initiate the dispute process. Personal statements added allow the subject to tell their side of the story. The dispute process allows subjects to dispute the factual accuracy of the report (for example, an incorrect adverse action code or payment date) and to argue whether a report was submitted in accordance with NPDB reporting requirements (for example, an adverse clinical privileges action lasting for 30 days or less; or the ineligibility of the reporting entity). Keep in mind that the NPDB guidebook states, "*The dispute process is not an avenue to protest a payment or to appeal the underlying reasons of an adverse action affecting the subject's license, clinical privileges, or professional society membership.*"

The NPDB is not an end all solution to protecting patients from negligent practitioners, but it has been a positive start. The NPDB, in conjunction with other sources of information, have been very influential for health care employers in decision-making regarding practitioners. The Health Care Quality Improvement Act of 1986 has met its intent of protecting patients from negligent practitioners by establishing the NPDB. Pharmacists should be aware that the NPDB encompasses more than just physicians and that claims payments and adverse credentialing decisions are reportable for pharmacists too. For complete information about the NPDB, please visit the NPDB's website at *www.npdb-hipdb.hrsa.gov*.

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Kyle J. Starostka is a Pharm. D. candidate at the University of Wyoming. Don R. McGuire Jr., R.Ph., J.D., is General Counsel at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

"Therapeutically Speaking..." Drug Therapy in Older Adults

Myron Weiner, RPh, PhD, Associate Professor, University of Maryland School of Pharmacy and
Sarah J. Brody, PharmD Candidate 2008

The elderly, defined as 65 years and older, are expected to increase in number to 70 million people by 2030, increasing from 13% to 20% of the population. Although they represent only 13% of the population at present, the elderly receive 35% of all prescription drugs and 40% of nonprescription medications. This disproportionate drug use also results in a higher incidence of adverse drug events. One student showed that seniors are more than twice as likely as non-seniors to experience an adverse drug reaction requiring treatment in an emergency room while they were almost seven times more likely to be hospitalized. To put this in practical terms, the number of adverse events in the elderly which results in hospital emergency department admissions approaches figures for auto accidents. One third of adverse reactions to drugs in the elderly were caused by 3 drugs: warfarin, insulin and digoxin.

In the first Institute of Medicine report dealing with medication errors, "To Err is Human," in 1999, medication errors were responsible for 44,000 deaths annually. In the more recent Institute of Medicine report from the Interdisciplinary Committee on Identifying and Preventing Medication Errors, it is estimated that one medication error occurs per hospitalized patient per day. Approximately 400,000 medication errors occur each year in hospitals, 800,000 in long term care facilities, and over 500,000 occurring among Medicare recipients in outpatient clinics, the majority of which are preventable. In the United States, Hanlon et al found 365 of 397 frail elderly patients received at least one inappropriate medication. Internationally, a Norwegian study found greater than 20% of hospital patient's deaths were associated with a prescription drug with the risk being higher in elderly patients. Greater than 50% of drug-associated deaths were due to drug errors, defined as patients receiving an inappropriate drug, a wrong dose, or the wrong route of administration. Older adults have an increased number of comorbidities, necessitating an increased number of chronic medications. Unsurprisingly, polypharmacy increases the risk of drug interactions and adverse effects in elderly patients.

Just what is an "inappropriate" drug? The term "inappropriate" has been applied to drugs found to have a greater potential for causing adverse events than drugs that were deemed equally-effective alternatives. Beers et al first listed criteria used to identify inappropriate medications for the frail elderly. They examined risk/benefit ratios of drugs in elderly patients and listed 33 drugs considered inappropriate in the elderly in nursing homes. This list was revised in 1997 when Beers applied the criteria to all people over the age of 65, not just frail elderly in nursing homes. Fick further updated the criteria by also listing drugs that were not only inappropriate, but should generally be avoided in the elderly because of ineffectiveness or their posing an unnecessarily high risk for older persons with a safer alternative being available. They listed 48 medications or classes of drugs to avoid, shown in Table 1. Studies using the criteria expressed by Beers et al and Fick et al have determined that 1 in 5 elderly Americans have received potentially inappropriate drugs. The suggested list of inappropriate drugs for older patients is a useful guide for community pharmacists.

There are many reasons why older adults are at greater risk for adverse drug events, including pharmacokinetic and pharmacodynamic changes associated with aging. Pharmacokinetics refers to how the body handles a drug, including absorption, distribution, metabolism and excretion. Of the four, absorption is the least affected by aging. Most studies indicate that drug absorption is not changed in the elderly, but absorption of vitamin B_{12}, iron and calcium via active transport mechanisms is decreased. The volume of distribution of drugs can be modified by changes in body composition that frequently changes with age. For example, lipid soluble drugs such as diazepam may have a longer half-life because of increased body fat associated with aging, resulting in an increased volume of distribution. Therefore, lower maintenance doses of diazepam are appropriate in the elderly. On the other hand, water-soluble drugs such as gentamicin, digoxin and theophylline, may have an increased blood level because of decreases in both total body water and muscle mass. In this case, loading doses and possibly maintenance doses of these drugs need to be decreased in the elderly.

Drug metabolism by some liver enzymes is less efficient in elderly patients. The cytochrome P450

content in liver biopsies of 226 patients was found to be decreased by 30% in patients over 70 years of age. However, the form of cytochrome P450 is important, since the content of cytochrome P4503A4 (CYP3A4), the isoenzyme responsible for the majority of clinically-used drugs, is primarily decreased compared to other forms. Thus, drugs that are primarily metabolized to inactive compounds by CYP3A4 can have higher serum concentrations and an enhanced pharmacological effect. Some of these drugs are alprazolam, triazolam, lovastatin, and atorvastatin. Furthermore, the "first pass" metabolism of many drugs is decreased with aging due to a reduction in both liver mass and hepatic flood flow. Medications affected by this include propranolol, labetalol, and lidocaine. With reduced metabolism, the patient may experience a heightened pharmacologic response.

A decline in renal excretion simply resulting from normal aging is the most common pharmacokinetic modification in elderly patients. Renal mass and renal blood flow decreases with age and the decrease in glomerular filtration rate (GFR) with age results in a clinically significant decrease in the excretion of drugs or active metabolites primarily excreted unchanged by the kidney. Since serum creatinine does not change with age because muscle mass and creatinine production decreases with age, it is not a useful indicator of renal function. Instead, creatinine clearance is used and estimated by the Cockcroft-Gault equation, the most commonly used equation to clinically estimate GFR in the elderly. It takes into account the patient's age, weight (in kg) and serum creatinine level. Therefore, drugs or pharmacologically active drug metabolites that are excreted by the kidneys may require dosage adjustment to prevent an adverse drug event. For example, drugs that have a narrow therapeutic index or margin of safety need to have their dosage decreased to compensate for their reduced clearance such as lithium, digoxin, aminoglycoside (e.g. gentamicin) and most cephalosporin (e.g. cefaclor) antibiotics and beta blocking agents (e.g. atenolol). Methotrexate is increasingly being used in patients with rheumatoid arthritis. It is eliminated primarily by renal excretion and its clearance is decreased with age.

Pharmacodynamics refers to the pharmacologic, or intended drug response, and it too may also be affected by aging (increased or decreased). Physiologic changes in the elderly that influence pharmacodynamic changes in drug responses are more difficult to predict and to study. While the majority of drug responses modified by aging are pharmacokinetic in nature, pharmacodynamic modifications exist. For example, the elderly have physiologic changes that increase the likelihood of falls with subsequent fractures, etc. These changes include a decrease in baroreceptor mechanisms caused by an increased thickness of blood vessels and a decreased blood vessel resiliency; there is an accompanying slowed reflex activity and a decrease in muscle strength. Thus elderly are susceptible to sedatives that can make the elderly dizzy and lose their balance, and to antihypertensives like alpha adrenergic blocking agents that cause postural hypotension. When comparing the clinical effect of a given serum concentration of diazepam, older adults show an enhanced drug effect when compared to younger counterparts. Therefore giving the same dose to in elderly and non-elderly subjects can lead to an increase in adverse effects in the aged. In addition to this modified sensitivity mechanism, metabolism, handled by the CYP3A4 system, is decreased in these drugs. Thus, a pharmacokinetic effect that allows increased plasma levels to cause an increased intensity and duration of action is also possible with these agents.

One of the most frequently prescribed sedative-hypnotics on the market is zolpidem (Ambien). The enzyme CYP3A4 is responsible for almost 60% of the metabolism of zolpidem, which may be reduced in older patients. This, combined with a likely exaggerated pharmacodynamic response to zolpidem can increase the risk of adverse effects with older adults. Olubodun et al demonstrated that zolpidem indeed is cleared much more slowly than in younger subjects (by approximately one third) and the half-life is twice as long. Their findings support the earlier recommendation that zolpidem dosage be decreased in the elderly. Failure to modify dosage of sedative-hypnotic agents could lead to sedation, confusion, ataxia, vertigo, falls, fractures, and overall health deterioration.

Warfarin certainly is a drug that is classified as having a narrow therapeutic index. Older adults have been shown to be more sensitive to the effects of warfarin, and may experience an increased anticoagulant effect. Conversely, the effects of both beta adrenergic agonists and blockers are reduced in the elderly. Thus, drugs like salbutamol (a beta-2 receptor agonist) and propranolol (a beta receptor blocker) show reduced responses to the same plasma levels of drug in elderly patients. The mechanism appears to be due to a reduced postreceptor event (i.e. a reduced cyclic AMP synthesis after receptor stimulation).

What can the pharmacist do in working with the elderly? Check their medications for appropriateness in terms of use and dosage, potential drug interactions, adverse effect monitoring or communication of what the patient should watch for and what to do if an effect occurs. Become familiar with the inappropriate drug lists shown in Table 1. The Centers for Medicare and Medicaid Services recently placed in its reference Guidance to Surveyors of Long Term Care Facilities

their adoption of the Beers' list of inappropriate drugs as an indicator of quality care in nursing homes. The community pharmacist is in an excellent position to partner with prescribers to optimize health care outcomes for older adults, and provide outstanding patient education on drug therapy.

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Complete reference list available upon request. Edited by: Mary Lynn McPherson, Pharm.D., BCPS
Professor, University of Maryland School of Pharmacy

Table 1 – Potentially Inappropriate Drugs in Older Adults

Propoxyphene (Darvon) and combination products
Indomethacin (Indocin and Indocin SR)
Pentazocine (Talwin)
Trimethobenzamide (Tigan)
Muscle relaxants and antispasmodics (e.g. methocarbamol (Robaxin), cyclobenzaprine (Flexeril)
Flurazepam (Dalmane)
Amitriptyline (Elavil) and combinations
Doxepin (Sinequan)
Meprobamate (Miltown and Equamil)
Long-acting benzodiazepines [e.g. diazepam (Valium), chlorazepate (Tranxene)]
Doses of short-acting benzodiazepines greater than lorazepam (Ativan), 3 mg; oxazepam (Serax), 60 mg; alprazolam (Xanax), 2 mg
Disopyramide (Norpace, Norpace CR)
Digoxin (Lanoxin) (not exceeding >0.125 mg/d except to treat atrial arrhythmias)
Short-acting dipyridamole (Persantine)
Methyldopa (Aldomet) and methyldopa-hydrochlorothiazide (Aldoril)
Reserpine at doses >0.25 mg
Chlorpropamide (Diabenese)
GI antispasmodic drugs [e.g. dicyclomine (Bentyl); propantheline (Pro-Banthine)]
Anticholinergics and antihistamines [e.g. diphenhydramine (Benadryl); hydroxyzine (Vistaril, Atarax)]
Ergot mesyloids (Hydergine) and cyclandelate (Cyclospasmol)
Ferrous sulfate>325 mg/d
All barbiturates (except Phenobarbital) except when used to control seizures
Meperidine (Demerol)
Ticlopidine (Ticlid)
Ketorolac (Toradol)
Amphetamines and anorexic agents
Long-term use of full-dosage, longer half-life, non-COX-selective NSAIDs: naproxen (Naprosyn, Avaprox, Aleve), oxaprozin (Daypro), and piroxicam (Feldene)
Daily Fluoxetine (Prozac)
Amiodarone (Cordarone)
Orphenadrine (Norflex)
Guanethidine (Ismelin)
Guanadrel (Hylorel)
Cyclandelate (Cyclospasmol)
Isoxsuprine (Vasodilan)
Nitrofurantoin (Macrodantin)
Doxazosin (Cardura)
Methyltestosterone (Android, Virilon, Testrad)
Thioridazine (Mellaril)
Mesoridazine (Serentil)
Short-acting nifedepine (Procardia and Adalat)
Clonidine (Catapres)
Mineral oil
Cimetidine (Tagamet)
Ethacrynic acid (Edecrin)
Desiccated thyroid
Amphetamines (excluding methylphenidate and anorexics)
Estrogens only (oral)
Long-term use of stimulant laxatives [e.g. bisacodyl (Dulcolax)]

Ref: Fick DM et al. Updating the Beers criteria for potentially inappropriate medication use in older adults. Arch. Intern Med. 2003; 163:2716-2724.

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Medication disposal guidelines: What pharmacists need to know

The One Minute Counselor

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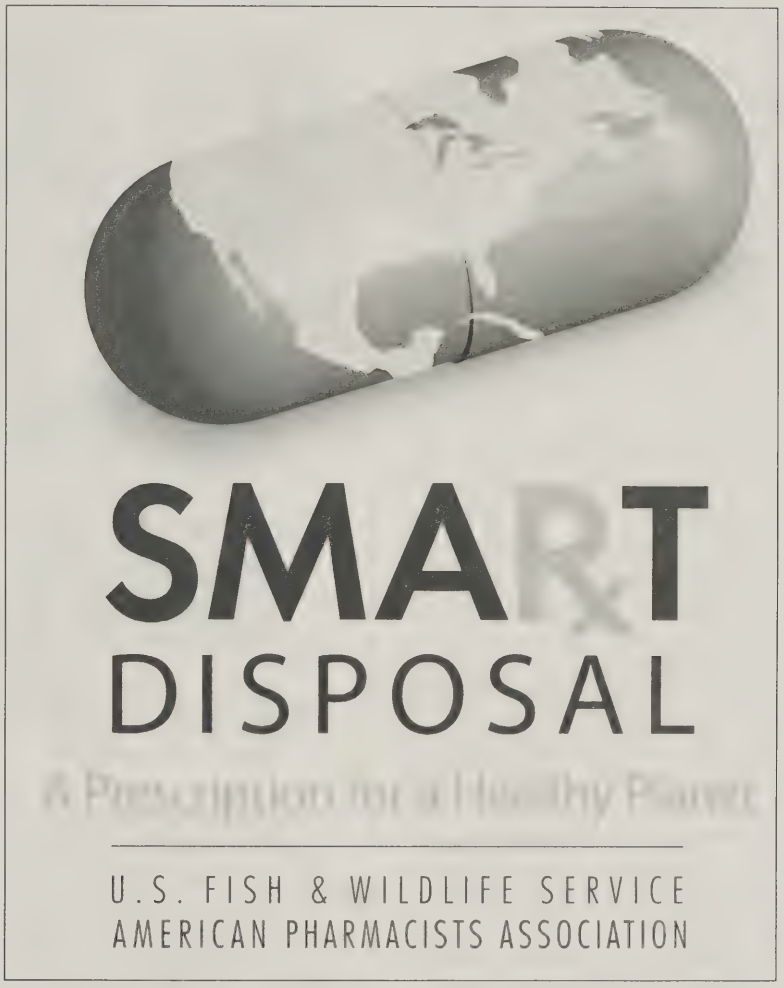
Trim along this line

Researchers writing in the November 2006 *Journal of the American Board of Family Medicine* surveyed 301 patients at an outpatient pharmacy and found that more than 50% reported storing unused or expired medications and 50% said they had flushed these medications. Fewer than 20% of respondents indicated that they had ever been advised by a health care provider on medication disposal.

APhA has teame d with the U.S. Fish and Wildlife Service (FWS) to begin to fill this knowledge gap among consumers regarding the proper disposal of unused medications. In July 2006, the two groups met, along with 50 government stakeholders, pharmaceutical manufacturers, conservationists, and environmentalists to discuss the various aspects of this problem. After subsequent meetings with key stakeholders, FWS and APhA created the SMARxT DISPOSAL program. A memorandum of understanding was signed at APhA2007 in Atlanta to launch the program, which aims to get the message to consumers NOT TO FLUSH.



What to tell your patients:

- Check for state or local medication collection or take-back programs.
- Check with hazardous waste facilities for disposal programs.
- DO NOT FLUSH, unless the medication label specifically says to do so.
- Crush unused solid medications and dissolve liquid ones.
- Mix with cat litter, coffee grounds, or other solid waste.
- Place in plastic bag and seal to avoid the risk of poisoning children or pets.
- Remove all identifying personal information from medication container.
- Place in garbage can.
- Proper disposal of medications will prevent them from being diverted and used illegally.

Take-back program

Thinking about organizing a prescription drug take-back program in your area? Pharmacists in Rock County, Wis., took the next step in safe medication disposal by setting up medication take-back days at two different locations in their county. APhA Trustee Jerald Sveum, BPharm, recently spoke with ***Pharmacy Today*** about the prescription drug disposal days. The group advertised the take-back days with posters announcing that medication drop-off was confidential and free. No preregistration was required, and volunteers provided drive-up service so donors did not have to leave their cars. The flyers also specified that radioactive materials, chemotherapy drugs, and sharps or needles would not be accepted.

Each drop-off donation was collected by a volunteer, who passed it on to a pharmacist. A team of pharmacists sorted the drugs into controlled and noncontrolled substances. The controlled substances were identified by name and quantity, logged in, and placed in special containers. Law enforcement officers sealed the containers when full; they took possession of all the collected drugs and transported them to an incineration facility, where they were weighed and marked for disposal.

During the first 4-hour session, volunteers collected 261 pounds of drugs. Sveum said, "We collected one medication from 1969." Organized by the Rock County Health Department in cooperation with local pharmacists, the Board of Health, and law enforcement, the program also collected 37 pounds of controlled substances in tablets and capsules and 3,050 mL in liquid form that first day. Sveum added, "The amount of controlled substances—especially schedule II medications—that were collected was substantial. It was really good to get these out of the homes where they could be available to children and teens and to do it in a way that protects the environment."

American Pharmacists Association
APhA

For a healthier environment, use SMAR$_x$T medication disposal

The One Minute Counselor™

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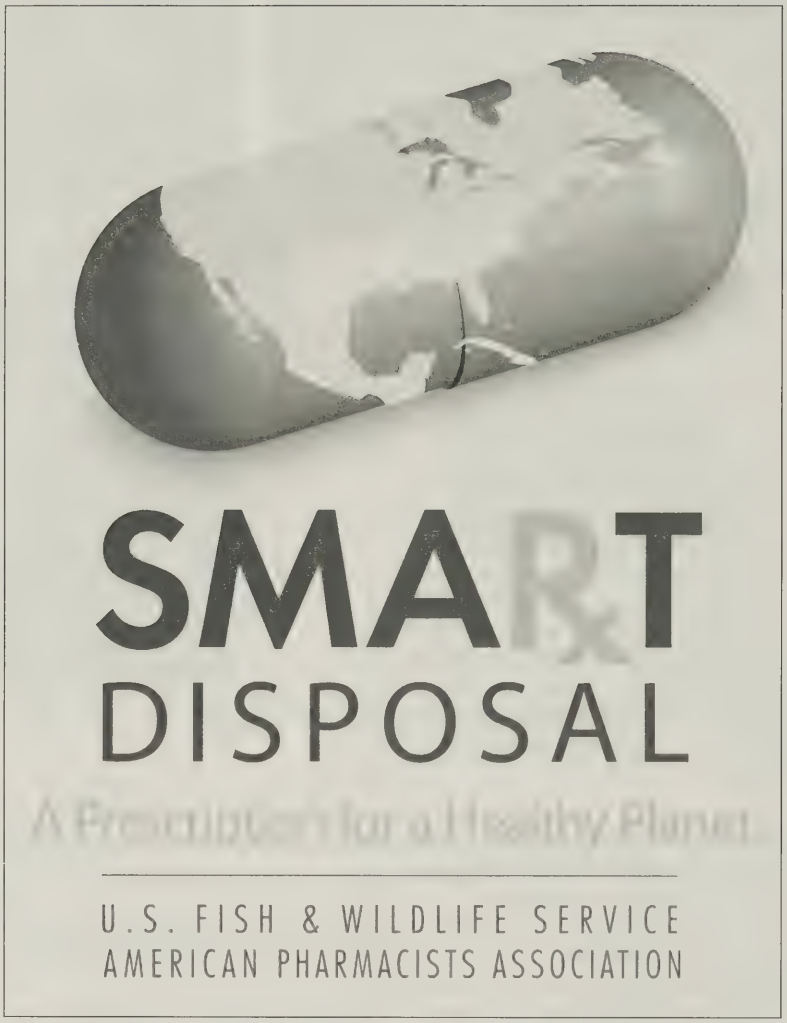
What do you do with your unused prescription medications? Do you flush them down the toilet or sink? What are the consequences of these drugs entering our sewer systems and making their way into our streams and lakes? A 2002 study by the Toxic Substances Hydrology Program of the U.S. Geological Survey found low concentrations of human and veterinary drugs in the waterways it sampled. Researchers found antibiotics, natural and synthetic hormones, detergent metabolites, plasticizers, insecticides, and fire retardants in waters downstream from urban areas and animal farmlands. One or more of these chemicals were found in 80% of the streams sampled. Half of the streams contained 7 or more of these chemicals, and about one-third of the streams contained 10 or more of the chemicals.



Don't flush

Most of these substances find their way into waterways through our sewer systems and septic tanks. Below are some ways you can help prevent this growing problem. Follow these simple steps, and check with your pharmacist if you are unsure about how to dispose of your medication.

1. Check for state or local medication collection or take-back programs.
2. Check with hazardous waste facilities for disposal programs.
3. If these options are not available, dispose of medications properly in the trash; DO NOT FLUSH unless the medication label specifically states to do so.

TOM MACKENZIE, U.S. FISH AND WILDLIFE SERVICE.

John A. Gans, PharmD, APhA Executive Vice President and CEO, demonstrates proper disposal of expired medications.

What you'll need:

- Cat litter or coffee grounds
- Sealable plastic bag
- Hammer and/or water

Before you toss

Here is what to do with your medication before you throw it in the trash:

- Crush unused solid medications and dissolve liquid medications.
- Mix the medication with cat litter, coffee grounds, or other solid waste.
- Place the medication in a plastic bag and seal to avoid the risk of poisoning children or pets.
- Remove all identifying personal information from the medication container.
- Place the bag and the drug container in a garbage can.

Remember:

Besides protecting the environment from drugs in the water supply, proper disposal of your medications will prevent them from being diverted and used illegally.

Trim along this line.

07-204

Continuing Education for Pharmacists

Volume XXV, No. 8

Women's Health: Guidelines for Prevention of Cardiovascular Disease

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., PharmD
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goal. The goal of this lesson is to discuss the 2007 American Heart Association (AHA) guidelines for prevention of cardiovascular disease (CVD) in women.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. differentiate cardiovascular morbidity and mortality data for men and women in the United States;
2. identify common risk factors for cardiovascular disease and recognize how their modification can benefit overall health;
3. demonstrate an understanding of the therapeutic role of aspirin in primary and secondary prevention of cardiovascular events; and
4. differentiate the AHA guidelines for prevention of CVD in women.

Gossel

Wuest

Background

More women in the United States die from cardiovascular disease (CVD) than from all forms of cancer combined, yet in one survey of women, only 8 percent of respondents considered CVD to be their greatest health threat. Prevention of CVD is paramount; fortunately, most CVD in women is preventable.

CVD in Women

The public health impact of CVD in women is not related solely to the high mortality rate. In the United States, 38.2 million women (34 percent) are living with CVD, and the population at-risk is even larger.

There are several reasons why mortality from CVD is so high in women. Women with symptoms of myocardial infarction (MI) are less likely than men to seek emergency treatment and more likely to die within a year of their event. Women may not experience the classic syndrome of angina characteristic for men. They are more likely than men, for example, to feel angina at rest and during sleep. Their pain may predominate in areas other than the anterior chest, including the lower jaw, both arms, shoulders, back, and epigastrium. Women are more likely to experience fatigue, nausea, vomiting, sweating, dyspnea, presyncope, or palpitations rather than chest pain. Women also experience more silent MIs, with nearly half of the events remaining unrecognized.

Women represented only 38 percent of subjects in National Institutes of Health (NIH)-funded cardiovascular studies. Women who are at risk for CVD are often not referred for appropriate diagnostic testing. Women with acute MI may be treated less frequently and less aggressively with thrombolytic and other cardioprotective therapy than men. They are less likely than men to receive aspirin within 24 hours of admission into a hospital with a cardiovascular event (83 versus 87 percent), have aspirin prescribed at discharge (84 versus 87 percent), or receive beta-blockers on admission (67 versus 70 percent). Women undergo fewer coronary angiography and revascularization procedures, and experience greater rates of complications and mortality following revascularization. Women are also less likely to participate in cardiac rehabilitation after an MI. Following an MI, women experience a higher death rate during hospitalization than men in similar age ranges. Within one year of a first MI, an estimated 38 percent of women versus 25 percent of men will die.

Guidelines for Prevention of CVD in Women

The first female-specific recommendations from the AHA for preventive cardiology were published in 1999 as an aid to health care professionals and their patients. The guide was intended to provide health care professionals with a comprehensive approach to patient care of women across a broad spectrum of risks.

Table 1
Guidelines for Prevention of Cardiovascular Disease in Women*

Lifestyle Therapy

Cigarette smoking. Do not smoke. Provide counseling, nicotine replacement & other therapy along with a behavioral program or formal smoking cessation program. (Class I, Level B)

Physical activity. Perform a minimum of 30 minutes of moderate-intensity physical activity every day of the week. (Class I, Level B) If overweight, perform a minimum of 60-90 minutes of exercise every day. (Class I, Level C)

Rehabilitation. Engage in a physician-directed comprehensive risk-reduction regimen if have a recent cardiovascular event or peripheral artery disease, or current/prior symptoms of heart failure & LVEF <40%. (Class I, Level B)

Dietary intake. Consume a diet rich in fruits & vegetables; whole-grain & high-fiber foods; oily fish (at least twice a week); limit saturated fat to <10% of energy (if possible to <7%), cholesterol to <300 mg/day, alcohol to 1 drink/day limit, & sodium intake to <2.3 g/d. Limit *trans*-fatty acids to <1% of energy. (Class I, Level B)

Body weight. Maintain a BMI between 18.5 and 24.9 kg/m^2 & waist circumference ≤35 in. (Class I, Level B)

Omega-3 fatty acids. Women with CHD may consume 850 to 1000 mg, in capsule form, of EPA and DHA; higher doses (2 to 4 g) if have high triglyceride levels. (Class IIb, Level B)

Depression. Women with CHD should be treated for depression when indicated. (Class IIa, Level B)

Major Risk Factor Interventions

Blood pressure. Maintain blood pressure of <120/80 mm Hg or lower through lifestyle therapy. (Class I, Level B) Drugs indicated when blood pressure is ≥140/90 mm Hg or even lower when chronic kidney disease or diabetes is present (≥130 mm Hg). Thiazides should be included for most patients unless contraindicated or there are compelling indications for other drugs. Initial treatment of high-risk women should be with β-blockers and/or ACE-I/ARBs, with additional drugs as needed. (Class I, Level A)

Lipid & lipoprotein levels. Strive for levels of LDL-C <100 mg/dL, HDL-C >50 mg/dL, triglycerides <150 mg/dL, and non-HDL-C (total cholesterol minus HDL cholesterol) <130 mg/dL (Class I, Level B). Women at high risk or with hypercholesterolemia should restrict saturated fat to <7% and cholesterol intake to <200 mg/dL. (Class I, Level B). Drugs indicated along with lifestyle therapy in women with CHD to achieve LDL-C <100 mg/dL (Class I, Level A) & similarly in women with other atherosclerotic CVD or diabetes or 10-yr absolute risk >20% (Class I, Level B). A reduction to <70 mg/dL is reasonable in very-high-risk women with CHD. (Class IIa, Level B)

Lipids in other at-risk women. Drugs indicated along with lifestyle therapy if LDL-C level is ≥130 mg/dL & there are multiple risk factors even if 10-yr absolute risk is 10% to 20%. (Class I, Level B) Use drugs with lifestyle therapy if LDL-C level is ≥160 mg/dL and multiple risk factors even if 10-yr absolute risk is <10% (Class I, Level B). Use drugs with lifestyle therapy if LDL-C level is ≥190 mg/dL regardless of presence or absence of other risk factors or CVD on lifestyle therapy. (Class I, Level B)

Lipids – pharmacotherapy for low HDL or elevated non-HDL, in high-risk women. Use niacin or fibrate therapy when HDL-C is low or non-HDL-C is elevated in high-risk women after LDL-C goal is achieved. (Class IIa, Level B) Consider niacin or fibrate therapy when HDL-C is low or non-HDL-C is elevated after LDL-C goal is achieved in women with multiple risk factors and a 10-yr absolute risk 10% to 20%. (Class IIb, Level B)

Diabetes mellitus. Follow lifestyle therapy and use drugs as indicated in women with diabetes (Class I, Level B) to achieve an HbA_{1C} <7%. (Class I, Level C)

Aspirin. Use aspirin therapy (75-325 mg/day) in high-risk women unless contraindicated. (Class I, Level A); Consider aspirin (81 mg/day or 100 mg every other day) in women ≥65 years of age if blood pressure is controlled & benefit for ischemic stroke and MI prevention outweigh risk of gastrointestinal bleeding and hemorrhagic stroke (Class IIa, Level B) and in women <65 years of age when benefit for ischemic stroke prevention outweighs adverse effects of therapy. (Class IIb, Level B)

β-blockers. Use indefinitely in all women after MI, acute coronary syndrome, or left ventricular dysfunction with or without heart failure, unless contraindicated. (Class I, Level A)

ACE-I/ARB. Use an ACE-I (unless contraindicated) in women after MI and those with evidence of heart failure or an LVEF ≤40% or with diabetes mellitus. (Class I, Level A). In women after MI and those with clinical evidence of heart failure or LVEF ≤40% or with diabetes who are intolerant of an ACE-I, an ARB should be used. (Class I, Level B)

Aldosterone blockade. Use after MI in women who do not have significant renal dysfunction or hyperkalemia who are already receiving therapeutic doses of an ACE-I and β-blocker, and have LVEF ≤40% with symptomatic heart failure. (Class I, Level B)

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*See Evidence-based guidelines for cardiovascular disease prevention in women: 2007 update. *Circulation*. 2007;115:1481-1501.

LVEF = left ventricular ejection fraction; BMI = body mass index; EPA = eicosapentaenoic acid; DHA = docosahexaenoic acid; ACE-I = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; LDL-C = low-density lipoprotein cholesterol; HDL-C = high-density lipoprotein cholesterol.

A drink equivalent is equal to a 12-oz bottle of beer, a 5-oz glass of wine, or a 1.5-oz shot of 80-proof spirit.

Classification/Levels of evidence:
Class I = Intervention is useful & effective
Class IIa = weight of evidence/opinion favors usefulness/efficacy
Class IIb = usefulness/efficacy is less well established by evidence/opinion
Class III = intervention is not useful/effective & may be harmful
Level A = sufficient evidence from multiple randomized trials
Level B = limited evidence from single randomized trial or other nonrandomized studies
Level C = based on expert opinion, case studies or standard of care

This was updated in 2004, and again in 2007. The 2007 update (Table 1) lists current clinical recommendations for prevention of CVD in women ≥20 years of age. Recommendations are based on an extensive review of the world literature, interpreted by experts in cardiology, epidemiology, family medicine, gynecology, internal medicine, neurology, nursing, public health, statistics, and surgery. The guidelines cover both primary and secondary prevention of chronic atherosclerotic vascular diseases.

Several important changes from the 2004 guidelines are noted. The approach to consideration of risk levels in the updated report places greater emphasis on lifetime risk, rather than on short-term absolute risk, as defined by the Framingham global score (see www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1494957). The 2007 guidelines acknowledge that most women are at risk for CVD, which underscores the relevance in maintaining a heart-healthy lifestyle. Moreover, some women are at high risk of future cardiovascular events because of established CVD and/or multiple risk factors. These women require more aggressive preventative therapy. Also, more definitive data concerning aspirin and hormonal therapies, and folic acid supplements have become available in recent years. Of note is that aspirin should be considered for all women for stroke prevention, depending on the balance of risks and benefits.

The ability to identify CVD in its earliest stages has continued to improve over the past several years resulting in further blurring of the difference between primary and secondary prevention. Instead of considering CVD as an all-or-none condition, there is increasingly stronger evidence now to consider it as a continuum of CVD risk. The 2007 update presents a scheme (Table 2) for a general approach to the female patient that classifies her as at high risk, at risk, or at optimal risk. Evidence that suggests CVD can be prevented in both women and men by eliminating the risks is overwhelming.

Generally, recommendations to prevent CVD in women do not differ from those for men. In some instances, the risk-reducing interventions recommended in these guidelines (e.g., use of ACE inhibitors and angiotensin receptor blockers for blood pressure control) are contraindicated in women who are pregnant.

Lifestyle Modification

Lifestyle modification includes healthy eating, cessation of smoking, regular exercise, and control of blood pressure. Up to 90 percent of all CVD in the U.S. may be attributed to these, and other, modifiable risk factors. Results of long-term prospective studies consistently confirm that persons with low levels of cardiovascular risk factors experience lifelong low levels of CVD and stroke. The Nurses' Health Study was a prospective observational investigation of 87,678 healthy middle-aged female nurses aged 34 to 65 years living in 11 states who were free of CHD (coronary heart disease), stroke, and cancer at onset. The women completed questionnaires at two-year intervals for six years, which sought information relative to their cardiovascular risk factors, extent of aspirin ingestion, and physician visits. Study endpoints were first occurrence of MI, stroke, all important vascular events, and cardiovascular death.

One outcome of the study was the observation that women who maintained a healthy diet, exercise regimen, and desirable body weight, and who did not smoke or consume more than a moderate amount of alcohol could reduce their risk of CVD by 84 percent. Nonetheless, only 3 percent of the women in the study (recall that all of them were health care professionals!) were included in that category.

Clearly, most causes of CVD are known and modifiable. No single risk factor can be considered in isolation. While each factor independently modifies the risk of CVD, they may work additively and/or synergistically to multiply an individual's risk. Risk stratification should incorporate known information about interaction between multiple risk factors, rather than simply counting the number of factors.

Table 2
Classification of CVD Risk in Women*

Risk Status and Criteria
High Risk
Established coronary heart disease
Cerebrovascular disease
Peripheral arterial disease
Abdominal aortic aneurysm
End-stage or chronic renal disease
Diabetes mellitus
10-Year Framingham global risk** >20 percent***
At Risk
≥1 major risk factors for CVD, including:
Cigarette smoking, poor diet, physical inactivity, obesity (especially central adiposity), family history of premature CVD [CVD at <55 years of age in male relative and <65 years of age in female relative], hypertension, dyslipidemia
Evidence of subclinical vascular disease (e.g., coronary calcification)
Metabolic syndrome
Poor exercise capacity on treadmill test and/or abnormal heart rate recovery after stopping exercise
Optimal Risk
Framingham global risk** <10 percent and a healthy lifestyle, with no risk factors

CVD = cardiovascular disease
*See Evidence-based guidelines for cardiovascular disease prevention in women: 2007 update. *Circulation.* 2007;115:1481-1501.
**See text
***Or at high risk on the basis of another population-adapted tool used to assess global risk

The Role of Aspirin in Prevention of Cardiovascular Events in Women

The second International Study of Infarct Survival (ISIS-2) demonstrated that aspirin provided clear and conclusive benefit in protecting against acute MI. The study enrolled 17,187 individuals (35 percent were women) who had symptoms of impending MI. Within 24 hours of onset of symptoms, those who received aspirin at 162 mg/day, had a 23 percent lowered risk for vascular death.

The benefit of aspirin for people who have no symptoms, principally women, is less clear since the majority of early trials have focused on men. There is, however, sufficient convincing evidence to affirm benefits for women.

Aspirin's cardioprotective benefit is believed to be due to its potent antiplatelet (i.e., antithrombotic) activity by inhibiting prostaglandin synthesis in platelet membranes to prevent platelet plug formation in atherosclerotic vessels. Additional sites and possible mechanisms for aspirin's role in reducing cardiovascular events include an antioxidant action, and effects on neutrophils, fibrinolysis, thrombin generation, and atherogenesis in higher doses. Since inflammation may also play an important role in atherosclerosis, and aspirin modifies inflammation, its anti-inflammatory action may help modify thrombosis.

The 2007 guidelines solidify the role of aspirin in primary prevention of CVD. The updated recommendation is to provide low-dose aspirin for women 65 years of age or older regardless of their cardiovascular risk status, if benefit is likely to exceed other risks. (Earlier guidelines did not recommend aspirin in lower risk- or healthy women). The new guidelines also recommend aspirin dosage of up to 325 mg/day for high-risk women of all ages. This represents an increase from the previously recommended 162 mg/day. Moreover, the guidelines recommend consideration of aspirin for women of all ages, including younger women who are at increased risk for cardiovascular events, including ischemic stroke.

Other Interventions

A number of interventions are deemed to be not useful/effective and may be harmful to CVD or MI prevention in women. These include:

- Hormonal therapy, including selective estrogen-receptor modulators (SERMs), should not be used for primary or secondary prevention of CVD;
- Antioxidant supplements, including vitamins C and E, and beta carotene, should not be used for primary or secondary prevention of CVD;
- Folic acid, alone or with vitamin B_{12} should not be used for primary or secondary prevention of CVD; and
- Routine use of aspirin in healthy women <65 years of age is not recommended for preventing MI.

Patient Counseling

All individuals should be evaluated by a physician before beginning daily aspirin dosing. Whether or not aspirin can be taken for the primary prevention of cardiovascular events should be based on an assessment of the patient's risk of an impending cardiovascular event without aspirin, absolute risk of gastrointestinal or intracranial hemorrhage with aspirin, and the patient's preference including willingness to comply with chronic daily dosing. Decisions concerning continuance of aspirin therapy should be reviewed at least every five years, or when new vascular risk factors are detected.

Individuals who have not been evaluated medically should not be encouraged to begin self-therapy with aspirin. There is a risk, albeit slight, for adverse reactions. There is one exception to the general rule advising against self-medication for cardioprotection. Since the extent of heart muscle damage corresponds directly to the rapidity of initiating aspirin therapy following onset of symptoms of MI, an uncoated aspirin tablet (325 mg) should be taken (best if chewed) at once if an MI is suspected.

The need for patient counseling and education is emphasized when patterns of aspirin utilization and mismedication are considered. Numerous surveys confirm the health benefits of aspirin in primary and secondary prevention of cardiovascular events, and that aspirin is underutilized. With respect to mismedication, 21 percent of patients in one study who were prescribed aspirin were mistakenly taking acetaminophen (11 percent) or non-aspirin NSAIDs (10 percent) instead of aspirin. The survey authors estimated that according to these data, as many as 1.3 million people ≥40 years of age may erroneously be taking acetaminophen or non-aspirin NSAIDs for cardiovascular protection, and another 1.4 million may be taking these agents along with aspirin. Only aspirin has been shown to confer cardioprotection to women and men.

Overview and Summary

CVD is the major cause of premature mortality in women living in the United States. Recently published guidelines are directed at reducing the death rate in this population.

Continuing Education Quiz

This month's questions are taken from the article on "Current Guideline for Home Use of Ipecac Syrup in Treatment of Ingested Poisons". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 3/15/10. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-07-003-H01.

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Date Completed _____
(*Required*)

The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education for pharmacists.

1. All of the following are reasons why mortality from CVD is so high in women, with the exception of:
   a. women have more severe MIs than men.
   b. women with symptoms of MI are less likely to seek emergency treatment.
   c. women may not experience the classic syndrome of angina.
   d. women are more likely to feel angina at rest.

2. All of the following are findings of NIH-funded cardiovascular studies with the exception of:
   a. women are less likely to receive aspirin within 24 hours of admission with a cardiovascular event.
   b. women who are at risk for CVD are often not referred for appropriate diagnostic testing.
   c. women are more likely to participate in cardiac rehabilitation after an MI.
   d. women undergo fewer coronary angiography and revascularization procedures.

3. All of the following are guidelines for prevention of CVD in women EXCEPT:
   a. may consume 850 to 1000 mg of EPA and DHA.
   b. do not take SSRI antidepressants.
   c. exercise a minimum of 30 minutes per day.
   d. do not smoke.

4. The guidelines recommend the use of which of the following lipid-pharmacotherapies for low HDL or elevated non-HDL in high risk women after LDL-C goal is achieved?
   a. Aspirin or aldosterone blocker
   b. BASR or statin
   c. Ezetimibe or ACE inhibitor
   d. Niacin or fibrate

5. The guidelines recommend that, in post MI women, acute coronary syndrome or left ventricular dysfunction, beta-blockers:
   a. can be used indefinitely, unless contraindicated.
   b. should never be used.

6. The 2007 guidelines place greater emphasis on:
   a. short-term absolute risk.
   b. lifetime risk.

7. The 2007 update to the classification of CVD risk for women has all the following categories of risk status and criteria EXCEPT:
   a. at high risk.
   b. at risk.
   c. at no risk.
   d. at optimal risk.

8. One outcome of the study was that women who maintain a healthy diet, exercise regimen and desirable body weight, and avoid smoking and excessive consumption of alcohol, can reduce their risk of CVD by:
   a. 24 percent.
   b. 44 percent.
   c. 64 percent.
   d. 84 percent.

9. The second International Study of Infarct Survival (ISIS-2) demonstrated that:
   a. aspirin provided clear and conclusive benefit in protecting against acute MI.
   b. aspirin provided little benefit in protecting against acute MI.

10. Hormonal therapy for women:
   a. is deemed to be useful for primary and secondary prevention of CVD.
   b. should not be used for primary or secondary prevention of CVD.

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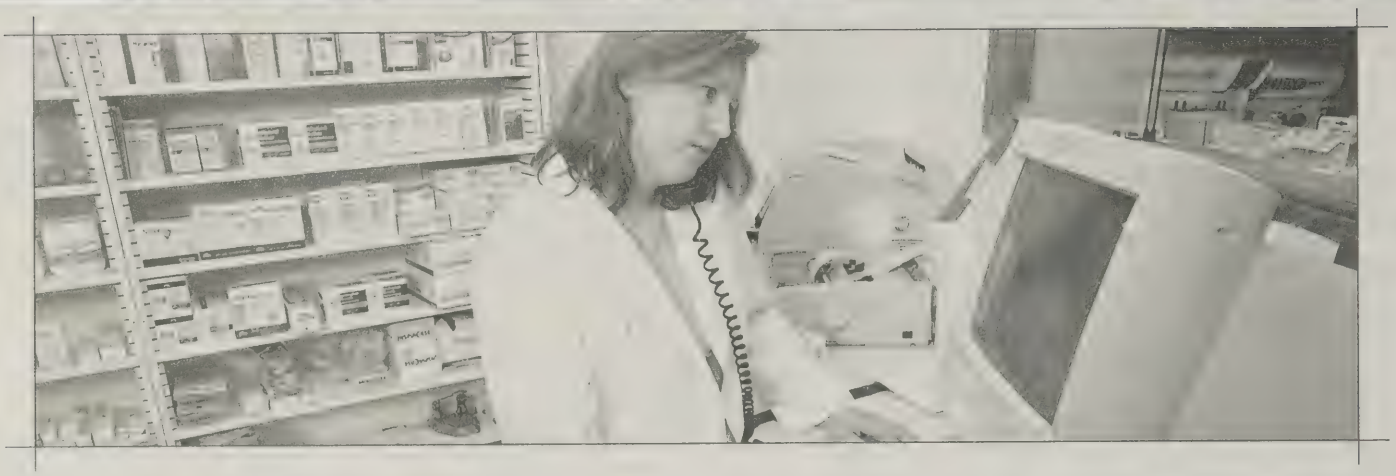

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MARYLAND PHARMACISTS ASSOCIATION OCT./NOV./DEC. 2007

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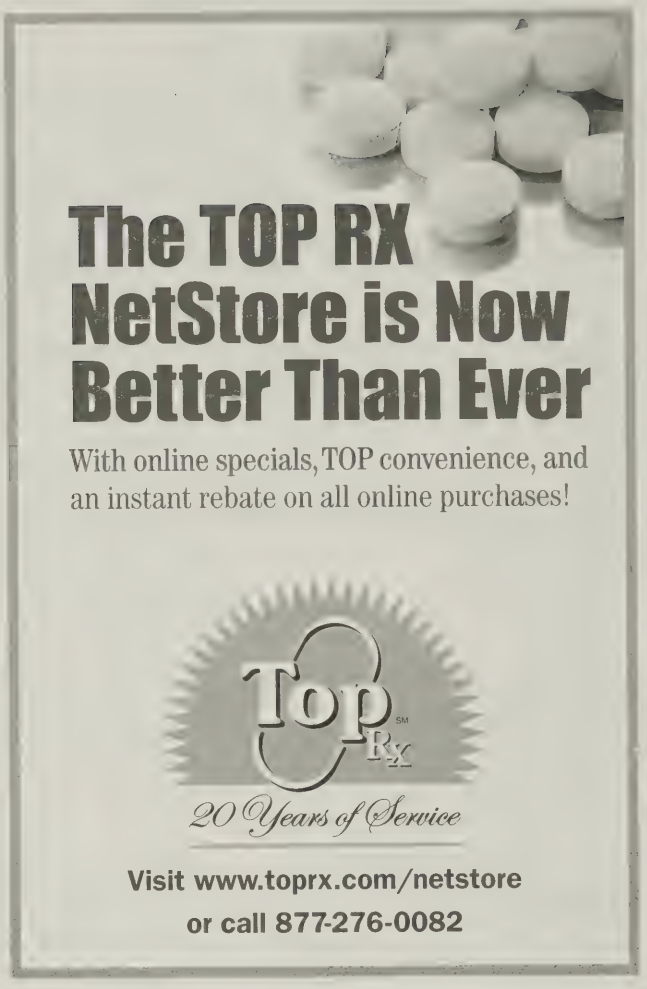
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Imagine...

Joseph Marrocco, P.D.
President

*In the words of one of the most influential songwriters and groups of recent generations, John Lennon of the Beatles, titled one of his classic works—**Imagine...***

I would share with you, my fellow pharmacist colleagues, that ***Involvement*** is essential in our profession, as it was in the lyrics and thoughts that Beatle, John was also striving to covey in that classic song.

Kristina Lunner, Vice President of government affairs for the American Pharmacist Association recently remarked "Our core task is to make very clear how pharmacists help people." Lunner pointed to physicians and nurses. "You see and feel the services they provide"..."any product component seems to be incidental to their primary role, which is providing expert clinical services."

I am proud to share with you that in Maryland, we have numerous colleagues who are providing these valued services to their patients. The Baltimore Sun newspaper recently had a splendid article with pictures relating Pharmacy Supervisor, Butch Henderson and his pharmacist team at Kleins in Harford County. A couple days later, the Sun featured a well detailed article that Professor Magaly Rodriguez de Bittner related Pharmacist involvement in clinical and community pharmacy practices.

MPhA Committee Chair, Christine Lee, proudly reports that her P3 Program has more employers on board, and is avidly seeking pharmacists to participate in providing these services. Special kudos to Communication Chair, Michelle Andoll, who aside from her own pharmacy, drives nearly and hour to offer the valued services to Upper Chesapeake Health Care. Kristen Fink, in addition to her full time Kaiser Pharmacist consultant position, drives back to eastern Baltimore County to provide these valued services to her Pharmacist, Dad's pharmacy practice in Essex.

Brian Hose, is providing P3 services and care, along with immunizations, in the Western Maryland Health System, in addition to serving as Committee Chair for the important Legislation arm of MPhA.

Hoai An Truong, a very recent Maryland Pharmacy School Grad has his Professional Development Committee highly engaged in Collaborative Drug Therapy Management that can facilitate writing protocols for Board Approval.

ASP President, Claire Leocha appeared with some of her fellow Maryland Pharmacy School students on WJZ-TV and was interviewed by Ron Matz.

Committee Chair, Doris Voigt, has an outstanding group of Pharmacist speakers and topics arranged for the MPhA Mid-Year Meeting, Sunday, January 27, 2008, at the Columbia, MD Sheraton Hotel—the week before Super Bowl. Doris has the unique ability to coordinate expert speakers with enlightening topics for all to enjoy.

...Imagine... *...Involve Yourself...* *...Your Profession...*

...Happy Holidays...

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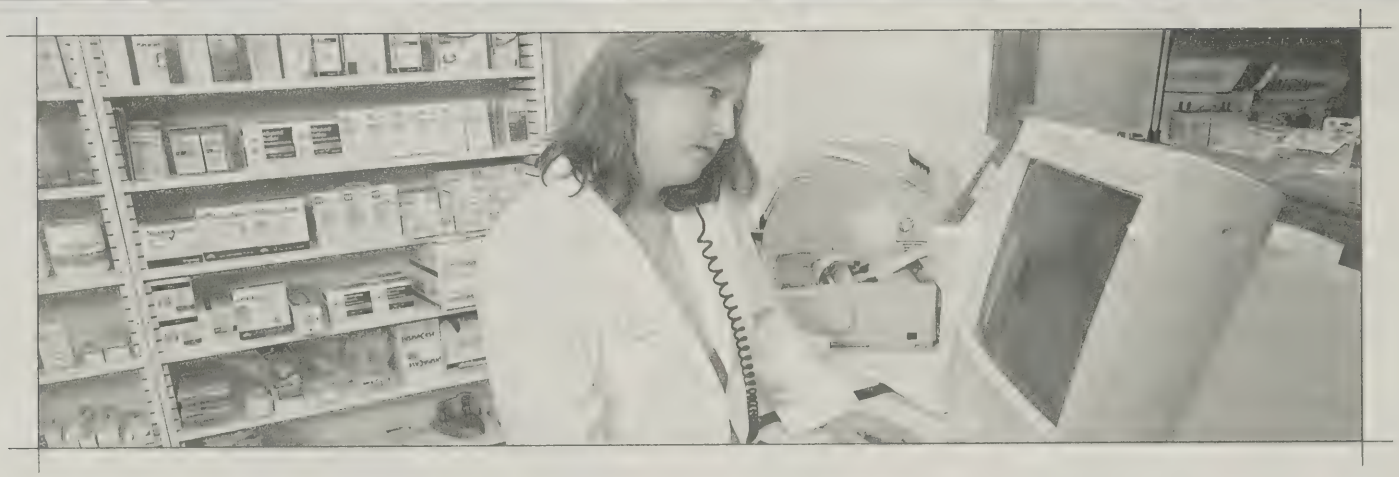

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Empowering Healthcare

Medication Management Across the Continuum of Care

Nicole Brandt, PharmD, CGP, BCPP, FASCP
Associate Professor, University of Maryland, School of Pharmacy

Appropriate medication management is a critical component of caring for older adults. The majority of individuals over the age of 65 live in the community, some live in nursing homes (NHs), and there is a rise in the number of individuals residing in assisted living facilities (ALFs). Patients residing in these facilities frequently have a high number of comorbid conditions and receive an average of 9 medications, putting them at high risk for medication misadventures.[1] This article will discuss the role and opportunities for pharmacists in NHs and ALFs.

Medication Management in Nursing Homes

Medications and pharmacy services are a critical part of the care provided to residents in nursing homes. The role of pharmacists in nursing homes has been well established, and includes aspects such as individual resident monthly medication regimen reviews, serving on the interdisciplinary team, and performing routine quality assurance audits. This role has been recently better defined with the implementation of updated guidance for nursing home surveyors with the publication of pharmacy "F-Tags" (F 329, F 425, F428 and F431) in December 2006. The term "F tag" refers to a regulatory requirement(s) that is found within the State Operations Manual (SOM). In addition to the regulation language, there is interpretive guidance for surveyors found at the F tag. The guidance provides assistance and direction to surveyors during their comprehensive assessment of the facility to determine if the facility is in compliance.

The updated guidance found at F tag 329, which focuses on unnecessary medications, moves the surveyor from a checklist approach of determining the presence of potentially inappropriate medications in older adults to a process of evaluating the impact of all medications on the care of each and every resident. This has drawn attention to the importance and role of the pharmacist as part of the interdisciplinary team to optimize medication management. Medication management includes recognition or identification of the problem/need; assessment; diagnosis/cause identification; management/treatment; monitoring; and revising interventions both pharmacologic and non-pharmacologic. The intent of the new guidance was to expand the surveyor's assessment beyond primarily antipsychotics and other psychopharmacological medications (e.g. benzodiazepines) to include an evaluation of all medications. The intent of the F-tag 329 regulation (use of unnecessary medications) is to ensure that all residents' are receiving only those medications which are necessary to treat or manage specified symptoms or conditions, allowing the resident to function at their most practicable level. Ensuring appropriate medication management includes consideration of (1) a specified indication for use, (2) monitoring parameters for benefits and potential adverse consequences, (3) appropriate dose and/or duplication of therapy, (4) statement of duration of use in accordance with clinical practice guidelines, current standards of practice or manufacturer's specifications for the stated indication, (5) evaluation for gradual dose reduction or tapering, and (6) procedures for prevention, identification, and reaction to the occurrence of adverse events. Pharmacists are held accountable for appropriate medication management by providing at least monthly medication reviews which is mandated by F-Tag 428.

Medication Management in Assisted Living Facilities (ALFs)

ALFs, unlike NHs, are regulated by each state; it is estimated that there are at least 36,000 ALFs in the United States.[2] The term used to describe ALFs varies from region to region and includes: assisted living homes, residential care facilities for the elderly, assisted living residence, and community residence facilities.

This makes it confusing to the patient as well as the medical community.

Further differentiating NHs and ALFs is the philosophy of care. NHs are highly regulated and follow more of a medical model with interdisciplinary care. ALF care is more of a social model which "maximizes consumers' independence, autonomy and dignity" as well as "minimizes the need to move when a resident's needs for services increases." [3] This can become a double-edged sword when it comes to medication management and the variability of supportive care services in the ALF. It is estimated that up to 77% of residents receive help with medication self-administration.[4] Since ALF's are regulated by the state rather than federal government, there is variation in the guidelines from state to state. In 2003, the Assisted Living Workgroup created a list of recommended policies concerning medication management in ALFs to help facilities create a medication management service that would work effectively and provide correct medications to the residents (Table I)[4]

It is important to note, in states that have chosen to implement some or all of these policies, variations still exist. Some of the variability among states includes:

- who can administer medications
- how much training one needs to administer medications,
- who can assess a resident for self-administration,
- how is assistance defined,
- is a medication review mandatory,
- who does the medication review, and
- how often a medication review should be performed

For instance in the State of Maryland, the regulations note the following:

> " *10.07.14.21 Medication Management*
>
> 1. The assisted living manager shall arrange for an on-site review by a registered nurse, appropriate authorized prescriber, or licensed pharmacist at least quarterly for each resident who:
>   - Self-administers medications; or
>   - Requires a reminder to take medications or physical assistance with opening and removing medications from the container.
>
> 2. If a resident requires that staff administer medications as defined in Regulation .02B of this chapter, and the administration of medications has been delegated to an unlicensed staff person pursuant to COMAR 10.27.11, the assisted living manager shall comply with COMAR 10.27.11 by arranging for an on-site review by the delegating registered nurse at least every 45 days. The delegating nurse shall make appropriate recommendations to the appropriate authorized prescriber, and the assisted living manager or designee."[5]

Importantly, this regulation is currently under revision and has provoked much discussion between the Office of Health Care Quality, Boards of Nursing and Pharmacy regarding medication management and pharmacy review.

Opportunities for Pharmacists

The idea of medication management has received increased focus from consumers, as well as pharmacists due to the requirements and opportunities provided by the Medicare Modernization Act of 2003. As the population ages, the number of medications will increase, leading to even more challenges with managing medications. Currently, it is estimated that one out of every 5 emergency room visits are thought to be due to medication related problems, and that the identification of medication related problems by a consultant pharmacist may save the healthy care system approximately $2,250 dollars a year per resident by preventing unnecessary trips to the ER.[6] In addition, pharmacists can assist in reducing medication errors as well as reduce the resident's medication costs by changing to generics, less expensive equivalent medications or discontinuing medications that are not necessary.

The intent of this article was to increase awareness of the vast opportunities for pharmacists across the continuum of care for older individuals, particularly in NHs and ALFs. Pharmacists are in a unique position to provide clinical services to older adults through various settings in which they reside.

Special thanks to Sarah Brody, Pharm.D. Candidate 2008 for assisting in compiling data and information on ALFs.

Edited by Mary Lynn McPherson, Pharm.D., BCPS
Professor, University of Maryland, School of Pharmacy

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[6] Clark TR. Prevention of medication-related problems in assisted living: role of the consultant pharmacist. *ASCP Issue Paper.* 2003.

Suggested Readings:

1) CMS website with SOM: http://www.cms.hhs.gov/manuals/downloads/som107_Appendicestoc.pdf
2) CMS website with Survey and Certification (S&C) Memos to States/Regions: http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage
3) Nursing Facility Survey and Regulations Briefing Room on ASCP website: www.ascp.com/public/pr/nfsurvey or www.ascp.com/som
4) Brandt N. Using Medications Appropriately access at: www.extendedcarenews.com from June 2007

Psychotropic Drugs...Then and Now

Mental illness has currently become a common medical diagnosis within the United States. The U.S. Department of Health and Human Services uses "patient care episodes" to estimate the number of people treated each year for mental illness. This tracks the number of people treated at psychiatric hospitals, residential facilities for the mentally ill, and ambulatory care facilities. In 1955, the government reported 1,675,352 patient care episodes. In 2000, patient-care episodes totaled 10,741,243. That is nearly a four-fold per-capita increase in the past 50 years. As the physicians' technique for diagnosing patients with a mental illness refines and improves, the amount of cases increases as well. This current rise in diagnosed patients could also be due to increased advertisements for antidepressants and other drugs, leading us to believe that the stigma of being treated is decreasing.

Back in the 1960s, John C. Krantz, Jr., a former professor of pharmacology and member of the U.S. Pharmacopeia, commented that psychotropic drugs accounted for 10 per cent of all the prescriptions written for in the United States. Most of these prescriptions were written for drugs such as phenothiazine derivatives including chlorpromazine, the rauwolfia alkaloids including reserpine, the alkyl diols including meprobamate, diphenylmethane derivatives such as hydroxyzine, benzodiazepams such as diazepam, and ethanol. These drugs that were used, exhibited a broad therapeutic affect on the central nervous system, treating most of the symptoms, however allowing more room for adverse side effects. Today, physicians and pharmacists generally treat anxiety-related mental illnesses with antidepressants and/or anti-anxiety medications that are more targeted to specific sites in the brain and receptors, ultimately decreasing the prevalence of nuisance side effects such as fatigue and drowsiness.

These drugs used during the 1960s and later were considered distinct from prior hypnotic therapies as they did not confer analgesia as do other drugs such as the alkaloids of opium. There was also no immediate hazard of addiction associated with these psychotropic drugs. However, these former drugs and even today's newer drugs still present suspicion as their use may be habit forming.

One formerly popular drug of the 1960s was chlordiazepoxide, also known by the trade name, Librium. This drug was a popular drug from the benzodiazepine series. Classified as a psycho-sedative; chlordiazepoxide evoked skeletal muscle relaxation without a pronounced hypnotic action. Today, chlordiazepoxide is generally used for mild to severe anxiety, acute alcoholism, and apprehension before surgery, however, its drowsiness and addiction potential limit its use today.

Another historical drug used for the treatment of anxiety and other mental illnesses was ethanol. Alcohol was quite possibly the oldest and most generally used of the minor psychotropic drugs back then. Today, the general public has become aware of ethanol's debilitating effects on the mind and body, including vital organs such as the liver.

Today, anti-depressants known as selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine (trade name Prozac®), make up for the majority of the mental illness therapeutics market. However, there are a variety of drug options to choose from, such as buspirone (trade name Buspar®). With the introduction of drugs such as buspirone, which is classified as an anti-anxiety agent that is not chemically or pharmacologically related to the benzodiazepines, barbiturates, or other sedative/anxiolytic drugs, physicians and pharmacists have succeeded in trying to treat mental illness while reducing the sedative side effects the could potentially decrease the patients' quality of life.

As we look back at the drugs used during the early 50s and 60s, we are reminded as to how drug evolvement has progressed over the years. Unfortunately, it also reminds us to how frequently mental illness has been diagnosed in our society. Yet, as pharmacists we will strive to continue researching and developing new psychotropic drugs, as Krantz and his associates did in the 1960s, in order to become one step closer to providing a better therapeutic and more safe response to all our mentally-ill patients.

Melike Tunc
Pharm.D. Candidate 2008
University of Maryland
School of Pharmacy

toxtidbits

the maryland poison center's monthly update. news. advances. information

November 2007

Haloperidol (Haldol®) Use in Toxicology

Imagine this... A patient presents to the emergency department with a history of Tylenol® PM overdose. She is wildly agitated with dilated pupils, flushed skin, dry mucous membranes, and minimal bowel sounds. You want to give her something to calm her down and have two options in front of you, haloperidol and lorazepam.

Which do you choose? All too often haloperidol is given to agitated or psychotic patients with a history of overdose. Many times it works and calms the patient down successfully, but what happens when the patient starts seizing? Haloperidol can lower the seizure threshold. Therefore, if a patient is suspected of overdosing on a substance that can also lower the seizure threshold (Table 1), haloperidol should be avoided. Benzodiazepines, usually lorazepam or diazepam, are alternatives. They are effective for sedation and have also shown benefit in patients with psychoses and alcohol withdrawal. Benzodiazepines are recommended for all toxin-induced seizures.

Table 1: Common toxins that can induce seizures and agitation in overdose

Aspirin	Tramadol (Ultram®, Ultracet™)
Tricyclic antidepressants	Bupropion (Wellbutrin®, Zyban®)
Diphenhydramine (Benadryl®)	Amphetamines
Cocaine	Venlafaxine (Effexor®)

Haloperidol has anticholinergic effects that can compound the effects of other drugs that possess anticholinergic effects and lead to increased agitation. Haloperidol interferes with the hypothalamic-pituitary axis and heat dissipation mechanisms. The administration of haloperidol to a patient suffering from the anticholinergic toxidrome can lead to significant hyperthermia. Haloperidol can also cause dystonic reactions.

The Maryland Poison Center is available 24-7 to answer all questions and assist in the management of all poisoned patients. Call 1-800-222-1222 to reach one of our certified specialists in poison information.

Bryan D. Hayes, PharmD, Clinical Toxicology Fellow

On November 19, 2007, the Drug Enforcement Administration (DEA) will publish in the Federal Register a Final Rule titled "Issuance of Multiple Prescriptions for Schedule II Controlled Substances." This rule is effective December 19, 2007.

This Final Rule amends DEA's regulations to allow practitioners to provide individual patients with multiple prescriptions for a specific schedule II controlled substance, written on the same date, to be filled sequentially. The combined effect of such sequential multiple prescriptions is that it allows a patient to receive over time up to a 90-day supply of that controlled substance. The Controlled Substances Act does not permit the refilling of schedule II controlled substances, requiring that a new prescription be issued for each quantity of the substance.

Following publication, the rule will appear on DEA's Office of Diversion Control website, www.DEAdiversion.usdoj.gov under "Federal Register Notices>Rules 2007."

U.S. Department of Justice
Drug Enforcement Administration
Mark W. Caverly, Chief
Liaison and Policy Section
Office of Diversion Control
www.dea.gov

Electronic Signatures and the Pharmacist's Responsibility

John F. Fader II, retired Judge of the Circuit Court for Baltimore County
Licensed Pharmacist

Those electronic signatures you have seen on prescriptions and those photocopies or printouts of prescriptions you have been receiving are governed by a regulation adopted by the Maryland Board of Pharmacy.

Here is what the law says is your legal responsibility: (1) to make sure that these and every prescription presented to you has an authentic signature; (2) to understand that electronic signatures have nothing to do with you unless you are a signatory to an electronic signature transfer agreement in compliance with Maryland law or otherwise comply with the directive of the Board; and (3) accepting a stamped or electronic signature photocopy (or what looks like a photocopy) does not fulfill your legal responsibility to assure the authenticity of the prescription unless you check to verify the prescription.

As a result of a student paper on "Electronic Prescribing" submitted by a pharmacy student as part of a MPhA rotation, the Association has asked about the legal authenticity of signatures transmitted electronically. Legal responsibility focuses on a Board Regulation (COMAR 10.34.20.02). Whatever method of transmission, the Regulation requires that it must ensure: (1) against alterations; (2) that confidentiality is preserved; (3) transmission of the exact information that comes from the prescriber; and (4) that there is no interference with the patient's freedom to choose a pharmacy. It is the responsibility of the pharmacist to assure the validity of every prescription and the signature of an authorized prescriber.

What this means as to electronic prescriptions is this:

First:

electronic transmission of a prescription (FAX, e-mail, etc.) must be through a communication method acceptable for commerce in Maryland. That could occur through compliance with the provisions of The Maryland Uniform Electronic Transactions Act – Com. Law §§21-101, et. seq. which requires you to be a signator to an agreement for electronic transmission. Ask you attorney about this.

This electronic transmission can also be accomplished through communication between the authorized prescriber or his/her authorized agent to the pharmacist through what the regulation calls "audio or visual interaction," which can mean a phone-in (except for CDS II) and other communication not detailed or explained in the regulation; and/or

Second:

in the words of the regulation "Is processed by a commercial intermediary, which guarantees the confidentiality and security of the transmission process in a manner approved by the Board." Whatever this can mean is a mystery. The FAX is self verifying. Whatever other programs or software the physicians are buying, you are not bound to accept. Write the Board (write – do not call), explain in detail the process that is at issue (sending literature on the program whenever available) and receive a written response before using that particular transmission process without a verbal confirmation. In time, the Board may well post acceptable programs on their web site.

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I certify that the statements made by me are correct and complete: Howard Schiff, Editor

Continuing Education for Pharmacists

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Meningococcal Disease and Available Vaccines

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., PharmD
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goals. The goals of this lesson are to discuss meningococcal disease and its prevention through immunization, and describe the vaccines available for this use.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. describe the incidence, etiology, communicability and clinical presentation of meningococcal disease;
2. differentiate between bacterial and viral meningitis;
3. list the current ACIP guidelines for preventing meningococcal disease through immunization; and
4. identify principles that define similarities and differences between the two meningococcal vaccines.

Background

Each year, approximately 1400 to 3000 cases of invasive meningococcal disease are reported in the United States. Although the incidence is relatively low (0.5 to 1.1 per 100,000 population), case-fatality rates and sequelae – conditions that accompany and follow the disease – among survivors are significant. Death follows in close to 14 percent of cases, even with appropriate antimicrobials and adjunctive therapies, with higher mortality rates of up to 40 percent in patients with sepsis. Sequelae include digit or limb amputation, neurologic deficits and seizures, hearing loss, and stroke in up to 20 percent of cases. Meningococcal disease has traditionally been considered a disease of children; however, over the past 15 years, rates of meningococcal disease among adolescents and young adults have increased.

Gossel

Wuest

Meningococcal Disease

Meningococcal disease is an acute, potentially severe illness caused by the bacterium *Neisseria meningitidis*. Despite the availability of an effective meningococcal vaccine for the past quarter century, meningococcal disease remains a leading cause of meningitis, sepsis, and other serious infections in industrialized nations and the developing world. The World Health Organization estimates that meningococcal disease was the cause of 171,000 deaths worldwide in 2000.

To describe meningococcal disease simply as "meningitis" or "spinal meningitis" is misleading, although meningitis is the most common presentation of invasive meningococcal infection and outcome from transport of the pathogen throughout the body via the blood. Septicemia occurs without meningitis in 5 to 20 percent of invasive meningococcal infections, and is the more serious clinical syndrome. The term *meningitis* describes an infection of the covering of the brain and spinal cord and can be caused by bacteria, fungi, viruses, or parasites.

Before the 1990s, *Haemophilus influenzae* type b (Hib) was the leading cause of bacterial meningitis. With routine use of conjugate vaccines that target, and therefore protect against Hib and *Streptococcus pneumoniae*, another common pathogen, *Neisseria meningitidis* has emerged as a leading cause of bacterial meningitis in the United States. Following onset of illness, disease progression is rapid; 60 percent of individuals are symptomatic for less than 24 hours before seeking medical care, and death may ensue within 48 hours.

N. meningitidis is a highly contagious aerobic, encapsulated, gram-negative diplococcus (i.e., meningococcus) closely related to *N. gonorrhoeae* and to several non-pathogenic *Neisseria* species, such as *N. lactamica*. *N. meningitidis* is characterized by at least 13 different serogroups (A, B, C, E-29, H, I, K, L, M, W-135, X, Y, Z). Serogroups are determined by differences in protein structure and capsular polysaccharides. Five serogroups (A, B, C, Y, and W-135) are responsible for most meningococcal disease worldwide.

Table 1
Signs and Symptoms of Bacterial Meningitis

- Stiff neck
- Fever
- Headache
- Nausea with or without vomiting
- Red or purple rash that does not change color if pressed on
- Confusion
- Fatigue or extreme sleepiness
- Seizures
- Irritability or lethargy (in infants, along with poor feeding, this may be the only symptom of meningitis)
- Recent flu-like illness or an ear or sinus infection may precede development of meningitis

Torpy JM, Lynm C, Glass RM. *JAMA*. 2007;297:122.

Serogroups B, C, and Y are the primary causes of meningococcal disease in the United States, each accounting for approximately one-third of cases in persons across all age spans. The primary serogroup(s) responsible for meningococcal disease varies by patient age. Serogroup B causes over 50 percent of cases in infants less than one year of age. Unfortunately, there is no vaccine for use in the United States that targets serogroup B meningococcus. Seventy-five percent of cases in persons 11 years of age or older are caused by serogroups C, Y, or W-135. It is noteworthy that meningococci have the ability to exchange genetic material that determines capsule production, and thus can switch from one serogroup to another. This may eventually become a mechanism for resistance of *N. meningitidis* to vaccines that target specific serogroups of the organism.

Communicability. Meningococcal disease is contagious. The bacteria are transmitted by droplet aerosol or secretions from the nasopharynx of colonized persons. The bacteria attach to and multiply on the nasopharynx mucosa. In a small number (<1 percent) of colonized persons, the organism penetrates the mucosal cells and enters the blood to spread throughout the body. In about 50 percent of bacteremic persons, the organism crosses the blood-brain-barrier into the cerebrospinal fluid (CSF) and causes purulent meningitis. A concomitant upper respiratory infection may be a contributing factor. Fortunately, *N. meningitidis* is not spread by casual contact or by simply breathing the air when a person with meningitis is present. Humans are the only natural reservoir of meningococcus; as many as 10 percent of adolescents and adults are asymptomatic transient carriers of *N. meningitidis*, most strains of which are not pathogenic. Meningococcal disease occurs throughout the year, however, the incidence is highest in the late winter and early spring.

Clinical Presentation. Early clinical manifestations of meningococcal disease are often difficult to distinguish from other, more common but less serious illness. Sudden onset of high fever, nausea with or without vomiting, intense headache, and stiff neck are common symptoms of meningitis in persons older than two years of age. A petechial rash with pink macules (colored spots on the skin that are not elevated above the surface) may be present. Blood bacterial loads rise quickly to high levels (>10^6/mL). This activates an inflammatory cascade, which leads to myocardial depression, endothelial dysfunction with extravasation of the circulating volume, and disseminated intravascular coagulation. Clinical signs of shock appear with poor capillary filling, cool and clammy skin, tachycardia, and oliguria (decreased urination). Hypotension is a late sign in infants and young children with its occurrence foreboding an ominous outcome. Leaking of pulmonary fluid leads to pulmonary edema, which may be heralded by tachypnea (increased respirations) and oxygen desaturation. Evolution of disease may proceed so rapidly that it outstrips any treatment that can be given.

Symptoms (Table 1) may develop over several hours, or take one to two days. Other symptoms may include photophobia (eye sensitivity to light) and an altered mental status. In infants, a slower onset of nonspecific symptoms occurs, and neck stiffness may be absent. Morbidity and mortality caused by meningococci are higher in older, versus younger, children. Whereas the proximal cause of death in younger adults is often brain herniation, older people often die of cardiorespiratory failure.

Early diagnosis and treatment are extremely important. Diagnosis is usually confirmed by growing bacteria from CSF collected by lumbar puncture or by detection of the meningococcal antigen in fresh CSF. Signs and symptoms of meningococcal meningitis are similar to those of other causes of bacterial meningitis, such as *H. influenzae* and *S. pneumoniae*; however, identification of the specific pathogen responsible is important for selection of appropriate antibiotic therapy.

Viral Meningitis. Symptoms of bacterial meningitis and viral meningitis are often the same. Viral ("aseptic") meningitis is caused by infection with one of several types of viruses. About 90 percent of viral cases are caused by members of a group known as enteroviruses, such as coxsackieviruses and echoviruses. Herpesviruses and the mumps virus can also cause viral meningitis. Between 25,000 and 50,000 hospitalizations due to viral meningitis are reported each year in the United States.

Viral meningitis is serious but rarely fatal in persons with a normal immune system. Symptoms last seven to 10 days and the patient usually recovers completely.

Enteroviruses are most often spread through direct contact with respiratory secretions from an infected person. The viruses can also be found in the stool of infected persons. The virus is spread through this route mainly among small children who are not toilet

trained or spread to adults while changing the diapers of an infected infant. The incubation period for enteroviruses is normally between three and seven days. Virus may be spread to other persons beginning about three days after infection until about 10 days after development of symptoms.

Currently, there is no vaccine or specific treatment for viral meningitis. Most patients recover completely on their own, with bed rest, plenty of fluids, and an analgesic/antipyretic to relieve headache and fever.

Meningococcal Vaccines

Two meningococcal vaccines are approved for use in the United States, both manufactured by Sanofi Pasteur. Menomune (Meningococcal polysaccharide vaccine; MPSV4) was licensed in 1978 for use in children older than two years and adults. Menactra (Meningococcal conjugate vaccine; MCV4) was licensed in the United States in 2005 and Canada in 2006 for use in children 11 years and older and adults through 55 years of age. Currently, FDA is considering MCV4 for use in children two to 10 years of age. Both vaccines mediate protection against meningococcal disease caused by serogroups A, C, Y, and W-135 by stimulating production of antibodies directed toward their surface polysaccharides.

Meningococcal Polysaccharide Vaccine. Each dose of MPSV4 consists of 50 µg each of the four purified meningococcal capsular polysaccharides, A, C, Y, and W-135. MPSV4 is available in single-dose (0.5 mL) and multiple-dose (5 mL) vials. MPSV4 is administered subcutaneously as a single 0.5 mL dose. It can be given concomitantly with other vaccines at different anatomic sites. Protective concentrations of antibodies usually are achieved within seven to 10 days of immunization. No boost in antibody titer occurs with repeated doses.

Meningococcal Conjugate Vaccine. MCV4 is a tetravalent meningococcal conjugate vaccine that contains 4 µg each of capsular polysaccharide antigens from serogroups A, C, Y, and W-135 individually conjugated to 48 µg of diphtheria toxoid protein carrier. MCV4 is available only in single-dose (0.5 mL) vials and is administered by intramuscular injection as a single 0.5 mL dose. Protective titers of antibodies are achieved within eight days of immunization. The length of protection is not currently known; therefore, booster doses are not recommended at this time. MCV4 can be administered at the same time as other vaccines. All vaccines should be given at separate sites with different syringes.

MCV4 confers advantages over MPSV4. First, persons receiving a second dose have a booster response (termed an *anamnestic* reaction, defined as the reappearance of antibodies that had previously existed and had disappeared from the blood). As noted earlier, this response is not found after a subsequent dose of MPSV4. Second, a longer duration of immunity than with MPSV4 is suggested. Third, experience gained from European studies with the monovalent meningococcal serogroup C conjugate vaccine that demonstrated a reduction in nasopharyngeal carriage of that serogroup suggests that MCV4 also will have similar effects.

Adverse Reactions. Adverse reactions to meningococcal vaccine are generally mild, consisting principally of localized pain and redness at the injection site lasting one to two days. These reactions occur in up to 48 percent of MPSV4 recipients and 59 percent of MCV4 recipients. Fever (100° to 103° F) within seven days of vaccination is reported in 3 percent of MPSV4 recipients and 5 percent of MCV4 recipients. Systemic reactions, such as headache and malaise, within seven days of vaccination are reported in approximately 60 percent of recipients of either vaccine; only 3 to 4 percent of recipients report these reactions as severe.

Guillain Barré syndrome (GBS) is a serious, rare neurological disorder that typically causes increasing weakness in leg, arm and other muscles and can be severe enough to require hospitalization. GBS usually resolves on its own, however some people may have residual neurological deficits. Confirmed cases of GBS associated with MCV4 have been reported. All individuals to date have recovered. While the number of cases suggest a small increased risk of GBS following immunization with MCV4, these findings need to be viewed with caution. At this time, neither the Centers for Disease Control and Prevention (CDC) nor FDA have determined with certainty whether the vaccine increases the risk of GBS in persons who receive the vaccine and, if so, to what degree.

Recommendations for Vaccine Use

The Advisory Committee on Immunization Practices (ACIP) to the CDC has published recommendations for the prevention and control of meningococcal disease. By the year 2008, the goal is for all adolescents to receive routine vaccination with MCV4 starting at age 11 years. For adolescents not previously vaccinated with MCV4 at their routine preadolescent healthcare professional visit, typically at 11 to 12 years of age, ACIP recommends vaccination before entrance into high school at approximately 15 years of age. Vaccination is optional for other adolescents to decrease their chance of contracting meningococcal disease.

ACIP also recommends routine vaccination with a meningococcal vaccine for individuals at a high risk for meningococcal disease including:

- college freshmen living in dormitories;
- microbiologists who are routinely exposed to meningococcal bacteria;
- U.S. military recruits;
- persons traveling to, or living in, a part of the world where

meningococcal disease is common, such as parts of Africa;
- persons with a damaged spleen, or whose spleen has been removed;
- anyone who has terminal complement component deficiency (an immune system disorder); and
- persons who might have been exposed to meningitis during an outbreak.

MCV4 is the preferred vaccine for persons 11 to 55 years of age who are at high risk, but MPSV4 can be used if MCV4 is not available. MPSV4 should be used for children two to 10 years of age, and adults over 55 years, who are at risk since MCV4 has not been adequately studied in these populations. Although college freshmen living in dormitories have a moderately increased risk of disease, most cases of which are caused by serogroup C, non-freshmen college students are at no greater overall risk for meningococcal disease than the general U.S. population. The reason why non-freshmen college students are not at increased risk is unclear. While persons with HIV/AIDS are at increased risk for meningococcal disease, ACIP does not currently recommend routine use of meningococcal vaccines in this population. For persons 11 to 55 years of age who have been previously vaccinated with MPSV4, revaccination with MCV4 is recommended if three to five years have lapsed since previous receipt of vaccination.

Routine vaccination with either MPSV4 or MCV4 is recommended to control meningococcal outbreaks caused by *N. meningitidis* serogroups A, C, Y, or W-135. An outbreak is defined as three or more confirmed or probable cases of meningococcal disease of the same serogroup in three or fewer months, resulting in a primary disease attack rate of 10 or more cases per 100,000 population. Either vaccine can be employed; however, MCV4 is preferred if the population to be vaccinated is between 11 and 55 years of age.

Persons who should not receive the meningococcal vaccine(s) include those who have ever experienced a severe (life-threatening) allergic reaction to a previous dose of either meningococcal vaccine or a severe (life-threatening) allergy to any vaccine component. Persons who are moderately or severely ill at the time the vaccine is scheduled should probably wait until they recover. People with a mild illness can usually receive the vaccine. Anyone who has ever had Guillain-Barré syndrome should discuss with their physician whether they should receive the MCV4 vaccine. Meningococcal vaccines may be given to pregnant women; however, MCV4 has not been studied in this population as extensively as MPSV4. MCV4 vaccine should be used only if clearly needed.

Medical Management of Meningococcal Disease

Meningococcal disease is treated with antimicrobials including rifampin, penicillin G, ampicillin, and third-generation cephalosporins. Mortality should be reduced to below 15 percent, although the risk is higher among the elderly. Therapy, based on the physician's experience, must be initiated early in the course of the disease, as soon as possible after the lumbar puncture has been completed. Treatment started before CSF collection makes it difficult to grow the bacteria in culture and thus confirm the diagnosis. Few penicillin resistant strains of meningococcus have been reported in the United States. Once *N. meningitidis* has been confirmed, penicillin alone is recommended. Individuals who qualify as close contacts of a person with meningococcal disease caused by *N. meningitidis* should receive an antimicrobial agent as prophylaxis. Treatment of contacts of a person with Hib meningitis is no longer recommended if all contacts four years of age or younger are fully vaccinated against Hib disease.

Vaccine Storage and Handling

Both vaccines are shipped in insulated containers to prevent exposure to freezing temperature. They should be stored at refrigerator temperature (35° to 46° F). Vaccine exposed to freezing temperature should not be used.

Single-dose vials of MPSV4 should be used within 30 minutes of reconstitution, and multidose vials should be discarded 10 days after reconstitution. MCV4 should not be drawn into a syringe until immediately before use.

Additional Information

A particularly helpful website that lists the ACIP general recommendations on immunization is found at www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm. Another site specific to meningococcal disease is www.cdc.gov/nip/publications/pink/mening.pdf. The complete ACIP recommendations for prevention and control of meningococcal disease are available at www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm.

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Continuing Education Quiz

This month's questions are taken from the article on "Meningococcal Disease and Available Vaccines". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 5/15/10. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-07-005-H01.

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(*Required*)

The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education for pharmacists.

1. Death reportedly follows meningococcal disease in close to which of the following percentages of cases?
   a. 4 percent
   b. 14 percent
   c. 24 percent
   d. 35 percent

2. Meningococcal disease is an acute, potentially severe illness caused by the bacterium:
   a. *Escherichia coli*.
   b. *Haemophilus influenzae*.
   c. *Neisseria meningitidis*.
   d. *Streptococcus pneumoniae*.

3. All of the following are correct descriptors of the causative organism referred to in question # 2 EXCEPT:
   a. aerobic.
   b. diplococcus.
   c. encapsulated.
   d. gram-positive.

4. The primary causes of meningococcal disease in the U.S. are:
   a. serogroups B, C, and Y.
   b. serogroups C, D, and X.
   c. serogroups D, E, and W.
   d. serogroups E, F, and V.

5. The clinical presentation of pink-colored spots on the skin that are not elevated above the surface are correctly referred to as:
   a. pustular rash.
   b. psoriatic rash.
   c. porphyrial rash.
   d. petechial rash.

6. Which of the following viruses is most likely to cause viral meningitis?
   a. Coxsackievirus
   b. Papillomavirus
   c. Rubeolavirus
   d. Varicellavirus

7. Meningococcal conjugate vaccine is:
   a. Menactra, MPSV4.
   b. Menactra, MCV4.
   c. Menomune, MPSV4.
   d. Menomune, MCV4.

8. Guillain Barré syndrome is a:
   a. cardiovascular disorder.
   b. lymphatic disorder.
   c. neurological disorder.
   d. pulmonary disorder.

9. The Advisory Committee on Immunization Practices to the CDC has recommended that by the year 2008, the goal is for all adolescents to receive routine vaccination with the vaccine referred to in question # 7 starting at age:
   a. 9 years.
   b. 11 years.
   c. 13 years.
   d. 15 years.

10. Once *N. meningitidis* has been confirmed, which of the following antibiotics is recommended?
   a. Cephalosporin
   b. Doxycycline
   c. Penicillin
   d. Rifampin

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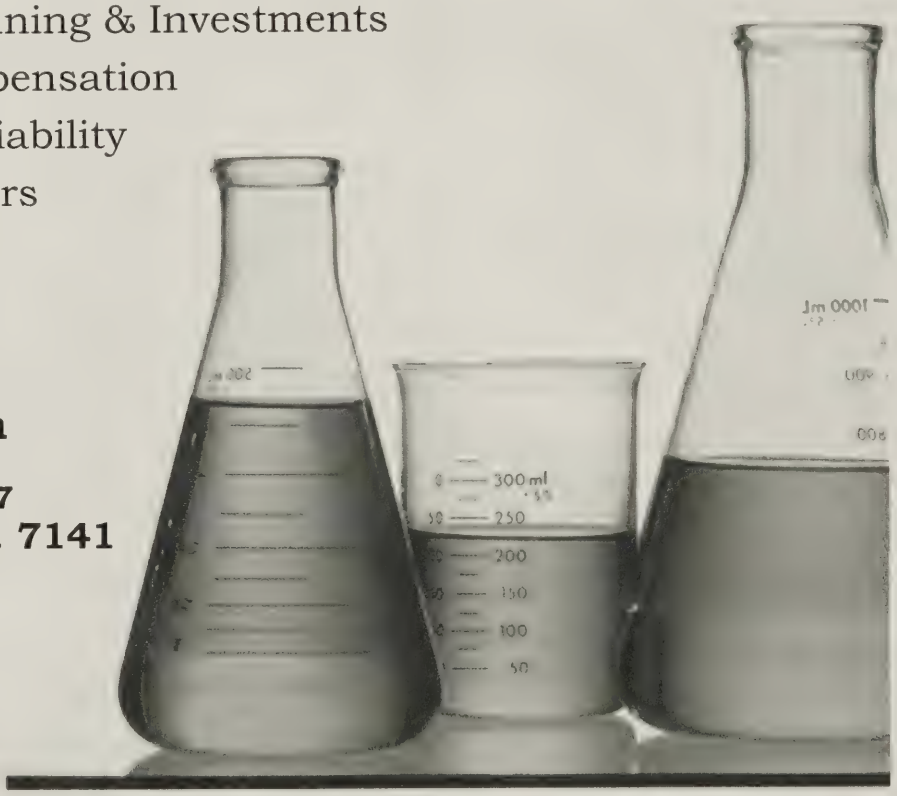

Dave Geoghegan
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